## EXHIBIT 71

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2	Exhibits 1-32
3	IN THE UNITED STATES DISTRICT COURT
4	FOR THE DISTRICT OF NEW JERSEY
5	
6	IN RE JOHNSON & JOHNSON TALCUM
7	POWDER PRODUCTS MARKETING, MDL NO.
8	SALES PRACTICES, AND PRODUCTS 16-2738(MAS)(RLS)
9	LIABILITY LITIGATION
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16	VIDEOCONFERENCE DEPOSITION OF
17	SONAL SINGH, M.D., M.P.H
18	Thursday, April 4, 2024, 9:03 a.m.
19	BEECHWOOD HOTEL
20	363 Plantation Street
21	Worcester, Massachusetts 01605
22	
23	
24	REPORTER: Sonya Lopes, RPR, CSR
25	

Golkow Technologies, A Veritext Division

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3 Ashcraft & Gerel, LLP	3 WITNESS: SONAL SINGH, M.D., M.P.H
4 Michelle A. Parfitt, Esq.	4
5 1825 K Street, N.W., Suite 700	5 EXAMINATION BY: PAGE
6 Washington, D.C. 20006	6 Mr. Martin 8
7 202.783.6400	7 Ms. Parfitt 275
8 mparfitt@ashcraftlaw.com	8
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1 INDEX 2 was duly sworn by the notary public, 3 EXHIBIT PAGE 4 Exhibit 22, 2019 article by Mohamed 5 Kadry Taher, et al191 6 Exhibit 23, 2021 article by Colette P. 7 Davis, et al207 Page 6 1 SONAL SINGH, M.D., M.P.H, 2 was duly sworn by the notary public, 3 examined, and testified as follows: 4 EXAMINATION 5 BY MR. MARTIN: 6 Q. Good morning, Dr.Singh. My name 7 Martin. I'm here on behalf of Johnson & J	Page 8
2 was duly sworn by the notary public, 3 EXHIBIT PAGE 4 Exhibit 22, 2019 article by Mohamed 5 Kadry Taher, et al191 6 Exhibit 23, 2021 article by Colette P. 2 was duly sworn by the notary public, 3 examined, and testified as follows: 4 EXAMINATION 5 BY MR. MARTIN: 6 Q. Good morning, Dr.Singh. My name	
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· · · · · · · · · · · · · · · · · · ·	ia Zaahamu
	- 1
8 Exhibit 24, 2021 article by Kiarash 8 LLC management. You understand you're	
10 Exhibit 25, April 2021 Health Canada 11 document227 10 report in the In re Johnson & Johnson talcu	iii powdei
12 Exhibit 26, 2022 article by Sean A. 12 A. That is correct.	
13 Woolen, et al230 12 A. That is confect.  13 Q. And you're also offering the same op	inione
14 Exhibit 27, supplementary table230  14 in the New Jersey multicounty litigation; is	
15 Exhibit 28, 2008 article by Anna H. 15 correct?	tilat
16 Wu, et al248 16 A. Yes. That is correct.	
17 Exhibit 29, 2019 article by Amy K. 10 A. Tes. That is confect.  17 Q. Okay. So I know you've been depose	rd
18 Harper, et al	
19 Exhibit 30, "EPA Asbestos Part 1; 19 belabor the rules. But just please give verb	
20 chrysotile asbestos; 20 answers like, not a shake of the head or r	
21 regulation of certain 21 the head to make it easy for your court re	
22 conditions of use under the 22 here.	porter
23 Toxic Substance Control Act, 23 Let me finish questions. I'll do my be	est
24 TSCA," document276 24 to let you finish your answers. You may w	
25 25 take a beat in case Ms. Parfitt wants to object	
Page 7	Page 9
1 INDEX 1 she does object, please still answer the ques	
2 anyway, unless she instructs you not to.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
3 EXHIBIT PAGE 3 And if you want to take a break at any	,
4 Exhibit 31, article by Kemi 4 time, just let me know. Just try not to take	
5 Ogunsina, M.D., et al283 5 break while a question's pending. If you ca	
6 Exhibit 32, article by Katie M. 6 the question, then we'll take a break.	
7 O'Brien, et al285 7 (Deposition notice, Exhibit 1, mark	ed)
8 Q. Doctor, have you seen this document	
9 *Exhibits returned to Mr. Martin 9 A. That is correct.	
10 Q. Okay. And have you seen exhibit	
11 Schedule A I'm sorry to the document,	just on
12 the next page?	-
13 A. That is correct.	
14 Q. Okay. And that schedule requests the	at you
15 produce certain documents. To the best of	-
16 knowledge, are all the were all the documents	-
17 Schedule A produced to us in advance of the	
18 deposition?	
19 A. That is correct.	
20 Q. Okay.	
	also
21 MS. PARFITT: Zack, if I may, we	and
21 MS. PARFITT: Zack, if I may, we 22 filed objections to the notice of deposition and 25 filed objections.	
22 filed objections to the notice of deposition 23 requested documents. So I'm not sure when	
22 filed objections to the notice of deposition	her you're

Page 10

MR. MARTIN: I am aware of the

2 objections.

1

- 3 MS. PARFITT: Thank you.
- 4 MR. MARTIN: I'm not going to mark that
- 5 as part of the file, but I'm aware of those.
- Q. But to the extent not barred by the
- 7 objections of counsel, you've produced everything
- 8 requested?
- A. That is correct.
- 10 Q. Okay. Did you bring any additional
- 11 materials with you today?
- A. Those are references -- those are all in my
- 13 -- but, you know, I've scribbled on them. That's
- 14 what it is.
- 15 Q. But there's no documents in there --
- 16 there's nothing in there that is not either in your
- 17 reference list or in the Dropbox that Ms. Parfitt
- 18 produced on Monday?
- A. No, as far as I know.
- 20 Q. How did you prepare for the deposition
- 21 today?
- 22 A. I read my report, and I reviewed my report.
- 23 I read my previous report. And where I had
- 24 questions for myself, I went through those
- 25 references and I, you know -- then yesterday

1 Dr. Cote, I was provided that. I skimmed through

- 2 it, you know, to the extent I reviewed -- yes -- and
- 3 have it.
- Q. I know you said you hadn't looked at your 4
- 5 previous deposition in advance of today. Have you
- 6 looked at that deposition since you gave it in
- 7 January 2019?
- 8 A. No.
- 9 Q. Okay. To the extent you remember what you
- 10 said in that deposition, is there anything you would
- 11 change or that you don't stand by?
- 12 MS. PARFITT: Objection. Form.
- 13 A. I think you'd have to, you know, point what
- 14 specifics you're asking for. But in terms of the
- 15 causal opinion, it is reflected in my expert report
- 16 -- supplemental report.
- Q. Okay. We will -- we might look at specific 17
- 18 parts --
- 19 A. Sure.
- 20 Q. -- later this morning. Beyond your two
- 21 expert reports, are there any writings in which you
- 22 set out opinions related to the purported
- 23 relationship between talcum powder and ovarian
- 24 cancer?
- 25 A. No.

1

- 1 evening, I met with the counsel for two, three hours
- 2 to discuss, prepare.
- 3 Q. And when you say "counsel," is that the two
- 4 counsel here in the room?
- A. That is correct.
- Q. And did you do that in person or over the 7 phone?
- A. In person.
- Q. Okay. Did they give you any additional
- 10 materials at that meeting?
- A. I don't recall.
- Q. Okay. You said you reviewed your two
- 13 reports in this case. Did you review your prior
- 14 deposition?
- 15 A. I did not.
- Q. Okay. Have you at any point reviewed any
- 17 of the depositions given by other experts in this
- 18 litigation?
- 19 A. I have.
- 20 Q. Okay. Which experts?
- A. I think at the time of the initial
- 22 deposition, I reviewed Dr. Diette.
- 23 Q. Diette, I believe, yeah.
- 24 A. Diette. Yeah. Sorry. His. And then for
- 25 this deposition, I was provided Dr. Moorman. And

- Page 13 Q. In 2018 and '19, you were charging \$600 an
- 2 hour. Is that still how much you charge?
- 3 A. A little bit more. 650.
- 4 Q. 650. Okay.
- 5 A. Inflation.
- Q. Understood. Understood. And beyond your 6
- 7 hourly rate, are there any other charges that you
- 8 have charged plaintiffs' counsel?
- A. No. 9
- 10 Q. No retainer?
- 11 A. No.
- 12 Q. Okay. Have you traveled at all for this
- 13 litigation?
- A. Yesterday I had to travel because of the
- 15 weather. So that wasn't preplanned. I stayed in
- 16 the hotel so that I could make it in time for you.
- 17 That's all.
- 18 Q. Okay.
- 19 A. I live a little bit out of town.
- Q. Never traveled outside of Massachusetts 20
- 21 for --
- 22 A. No. No.
- 23 Q. -- for the case. Okay. I have Exhibit 2
- 24 here. This is something that was produced to us on
- 25 Monday by Ms. Parfitt.

Page 14	Page 16
1 (Invoice, Exhibit 2, marked)	1 A. I cannot. I mean, it's what 2018,
2 Q. Does this invoice reflect all of the work	2 2019? Yeah.
3 that you have done on this case since your last	3 Q. Your last deposition was January of 2019.
4 deposition in January of 2024 (verbatim)?	4 A. I cannot estimate.
5 MR. TISI: I'm sorry. I didn't realize	5 Q. Okay. Not even a ballpark number?
6	6 MS. PARFITT: Objection. Form.
7 MR. MARTIN: I'm sorry. This is two-	7 A. No, not really.
8 sided, for anyone who hasn't seen that.	8 Q. Do you know if it was more or less than a
9 A. Yeah. This reflects the invoice I	9 hundred thousand dollars?
10 submitted at that time. I haven't submitted any	10 MS. PARFITT: Objection. Form.
11 other invoices.	11 A. Probably more.
12 Q. That wasn't quite my question.	12 Q. Do you know if it's more or less than
Does that reflect all the work you've	13 \$200,000?
14 done	14 MS. PARFITT: Objection. Form.
15 A. No.	15 A. I don't know that.
16 Q since okay. Does it reflect all the	16 Q. Approximately what percentage of your
17 work you had done from January of 2019 through the	17 income last year came from litigation work?
18 date of this invoice?	18 MS. PARFITT: Objection. Form.
19 A. Yeah.	19 A. Last year?
Q. Okay. So you didn't do any work after your	20 Q. The year 2023.
21 deposition and before September of last year?	21 MS. PARFITT: Same objection.
22 A. No.	22 A. I can't recall the specifics of it.
23 Q. Okay. Can you estimate approximately how	23 Q. Okay. Again, more or less than 30 percent?
24 many hours you've spent on this case since the date	24 MS. PARFITT: Objection. Form.
	-
25 of this invoice, which is November 15th of 2023?	25 A. You know, I have other sources of income.
25 of this invoice, which is November 15th of 2023?  Page 15	25 A. You know, I have other sources of income.  Page 17
	,
Page 15	Page 17
Page 15  1 A. I would say 40, 45 hours. I don't have an	Page 17 1 You know, I do trading. I do other work. So I
Page 15  1 A. I would say 40, 45 hours. I don't have an  2 exact number.	Page 17 1 You know, I do trading. I do other work. So I 2 don't keep track of I mean, I produced the
Page 15  1 A. I would say 40, 45 hours. I don't have an  2 exact number.  3 Q. That's fine. That's ballpark. So if I	Page 17 1 You know, I do trading. I do other work. So I 2 don't keep track of I mean, I produced the 3 invoices that you asked for.
Page 15  1 A. I would say 40, 45 hours. I don't have an  2 exact number.  3 Q. That's fine. That's ballpark. So if I  4 were if I could do mental math, I probably	Page 17  1 You know, I do trading. I do other work. So I  2 don't keep track of I mean, I produced the  3 invoices that you asked for.  4 Q. What is your salary from the University of
Page 15  1 A. I would say 40, 45 hours. I don't have an  2 exact number.  3 Q. That's fine. That's ballpark. So if I  4 were if I could do mental math, I probably  5 wouldn't be a lawyer. But that reflects	Page 17  1 You know, I do trading. I do other work. So I  2 don't keep track of I mean, I produced the  3 invoices that you asked for.  4 Q. What is your salary from the University of  5 Massachusetts?
Page 15  1 A. I would say 40, 45 hours. I don't have an  2 exact number.  3 Q. That's fine. That's ballpark. So if I  4 were if I could do mental math, I probably  5 wouldn't be a lawyer. But that reflects  6 approximately 650 times 45 \$29,000 worth of	Page 17  1 You know, I do trading. I do other work. So I  2 don't keep track of I mean, I produced the  3 invoices that you asked for.  4 Q. What is your salary from the University of  5 Massachusetts?  6 MS. PARFITT: Objection. Form. What's
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MS. PARFITT: Objection. Form. It's

25 the same question. Non-litigation income would

24

25

24 work since your last deposition in 2019?

MS. PARFITT: Objection.

Page 21

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Page 18 1 include salary.

- A. I didn't prepare for sort of, you know,
- 3 monetary, which income from where. I produced what
- 4 was here, and that's what I was prepared to answer.
- MR. MARTIN: I think it's relevant to
- 6 credibility, but we'll move on.
- 7 MS. PARFITT: Thank you.
- 8 MR. MARTIN: Let's look at your CV.
- 9 (Curriculum vitae, Exhibit 3, marked)
- 10 Q. So this is the CV that was produced to us
- 11 on Monday. And I believe it's current as of this
- 12 month. Is there anything that looks not current to
- 13 you in that?
- 14 A. No.

1 sciences?

3 know.

2

4

- 15 Q. Okay. So there are a couple of changes
- 16 since the time of your last deposition that I want
- 17 to talk about. The first is on page 1. And it's
- 18 your role as associate professor in the division of
- 19 health systems sciences. Okay. You started that
- 20 role in October of 2022?

5 doing at the university?

A. Yeah.

- A. Yeah. It was more, you know -- we were at
- 22 Meyers. And it was more an incorporation than an
- 23 institute into the school of medicine.
- Q. Okay. So just so I'm clear, it was more
- 25 the creation of a formal division of health systems

A. Exactly. Yes. It's very new. It's, you

Q. It incorporates work you'd previously been

Q. Okay. Does it incorporate work from the 8 Department of Family Medicine & Community Health,

A. Yes.

- 2 Q. Okay. What did that course entail,
- 3 generally?
  - A. It entails starting out with first years,
- 5 usually teaching them about study designs, how to
- 6 review a case control study, cohort study,
- 7 randomized trials, and, you know, bias, confounding
- 8 So it's -- yeah.
- Q. Just to be clear, when you say first-year
- 10 students, you mean first-year medical students, not
- 11 first-year residents.
- A. No. These are medical students. They 12
- 13 could be nursing students as well.
- Q. Okay. Approximately how many students were
- 15 in that class?
- 16 A. I don't recall. You know, usually --
- 17 sometimes it's 15.
- Q. And is there a reason that you stopped
- 19 teaching the class in 2022?
- 20 A. Yeah, there is. Because the class
- 21 coincided with my clinical days so that it was sort
- 22 of -- I had to choose between teaching.
- Q. The class is still existing. It's just
- 24 taught by someone else?
- 25 A. It is.

Page 19

Q. Can you guys flip to page 7, please?

1 2 MR. TISI: Can I just say I'm getting a

3 note that your voice is really muffled.

- 4 MR. MARTIN: Off the record.
- 5 (A break was taken)
- MR. MARTIN: Back on the record. So
- 7 while we were off the record, Ms. Finken asked that
- 8 Ms. Parfitt's objections be for all plaintiffs'
- 9 counsel. So just memorializing that now that we're
- 10 on the record.
- 11 A. So, you know, the way it was, we -- there
- 12 was Meyers Health Institute maybe at that time that

9 the Department of Quantitative Health Sciences, or

- 13 I was deposed. And the institute -- medical school
- 14 brought in people who do health systems research
- 15 into one institute. And that's why it's reflected
- 16 there.

10 both?

- 17 Q. Actually, it's on the same page.
- 18 A. Sure.
- 19 Q. I'm sorry. No. It's not. It's on page 3,
- 20 teaching and classroom activities. It looks like
- 21 you started to teach a course at the medical school
- 22 since your last deposition.
- 23 A. That is correct.
- Q. And is "Clinical epidemiology for medical
- 25 students" the name of that course?

- Q. We were on page 7 of your CV, and at the
- 12 top of page 7 it asks for submitted grants. First
- 13 of all, can you explain what you mean by "submitted
- 14 grants"?
- 15 A. Sure. So grants submitted are those that
- 16 are being reviewed at the NIH, so these were
- 17 submitted for NIH consideration. You see at the top
- 18 "National Institute of Aging." So these have not
- 19 been funded yet. They will be reviewed probably in
- 20 April sometime. Then we'll know. So a department
- 21 likes to know, you know "Are you working? Are you
- 22 submitting new grants?"
- Q. Fair to say, these aren't things -- well,
- 24 beyond submitting the funding proposal, these aren't
- 25 things on which you're doing active research.

6 (Pages 18 - 21)

Page 22

- 1 A. Yeah. No. No. The ones that are active 2 are listed right below that.
- 3 Q. We'll get to those. So is this submitted
- 4 grant related to talc at all?
- 5 A. No.
- 6 Q. Is it related to ovarian cancer at all?
- 7 A. No.
- 8 Q. Okay. As you mentioned, below the
- 9 submitted grant, there are three active grants, all
- 10 of which postdate your last deposition. Are any of
- 11 those related to talc --
- 12 A. No.
- 13 Q. -- to ovarian cancer or cancer more
- 14 generally?
- 15 A. No.
- 16 Q. All right. And then on "completed grants
- 17 and contracts," going from page 7 and into page 8, I
- 18 believe there are three or four that postdate your
- 19 last deposition. I think three that started after
- 20 your last deposition, those would be the three that
- 21 are on page 7 or begin on page 7. Do you see that?
- 22 A. Yes.
- 23 Q. And do any of those grants have to do with
- 24 talc?
- 25 A. No.

Page 23

- 1 Q. Okay. Cancer?
- 2 A. No.
- 3 Q. Okay. Let's turn to page 10. Since your
- 4 last deposition in 2016 (verbatim), it looks like
- 5 you've joined the editorial board of two journals:
- 6 Frontiers in Drug Safety and Frontiers in Primary
- 7 Care and Family Medicine. Is that correct?
- 8 A. That is correct.
- 9 Q. And you've left the editorial board of
- 10 Evidence-Based Medicine?
- 11 A. That is correct.
- 12 Q. Okay. Since you joined the editorial board
- 13 of Frontiers in Drug Safety, are you aware of
- 14 whether they've published any articles related to
- 15 talc?
- 16 A. I'm not aware of a specific journal, but
- 17 I'm aware that Frontiers had a publication on that.
- 18 I'm not sure if it's on drug safety, but the group
- 19 of journals has it.
- Q. Can you explain that a little bit more?
- 21 Frontiers is a group of journals of which there are
- 22 several topical journals. Is that more or less
- 23 correct?
- 24 A. Yes. Yes.
- 25 Q. You're not aware of whether the two topical

- Page 24
- 2 anything on talcum powder?
- 3 A. Yeah. Yeah.
- 4 Q. Okay. Do you know if the two -- if either

1 journals for which you were an editor published

- 5 of the journals for which you're an editor have
- 6 published anything on asbestos since you joined?
- 7 A. No. I don't keep track of all the articles
- 8 in the journal. I'm on the editorial board. So I
- 9 get asked to review certain articles every year, at
- 10 least six. That's sort of the mandate, so.
- 11 Q. So just so I understand the process, your
- 12 job is essentially when someone submits an article
- 13 for publication, you're one of the peer reviewers
- 14 for the journal?
- 15 A. No. I'm the handling editor. So I get to
- 16 ask, you know, if it's, you know -- the editor-in-
- 17 chief looks at the editorial board and -- so I'm not
- 18 the editor-in-chief. I'm an editorial board member.
- 19 And they send it to me, say "Okay. You are the
- 20 handling editor." And you send it out for review,
- 21 comes back. And I may be asked to review, too, so
- 22 there's two sort of aspects of the job.
- 23 Q. That's helpful. Thank you. Assume you
- 24 haven't personally seen any articles --
- 25 A. No.

- 1 Q. -- related to talc or asbestos. Okay. I
- 2 want to look at your publications since 2019. Do
- 3 you recall approximately how many things you've
- 4 published since 2019?
- 5 A. Not really.
- 6 Q. Okay. So I went through your CV. Let's
- 7 turn to page 26 first. Is it correct there have
- 8 been no books or monographs since 2019?
- 9 MS. PARFITT: Objection. Form.
- 10 Q. Have you published any books or monographs
- 11 since 2019?
- 12 A. No.
- 13 Q. Okay. Turning to page 28. First of all,
- 14 can you explain what the difference between a peer-
- 15 reviewed educational publication and a what we might
- 16 call traditional peer-reviewed publication is?
- 17 A. Yeah. So for us, you know, in the academic
- 18 world, we try to make a distinguish (verbatim)
- 19 between, you know, research articles that are based
- 20 on original data, so that, you'll see that in the
- 21 original research section.
- Others are editorials. We'll try to place
- 23 into the editorial section. And then educational
- 24 articles are if -- say I'm the expert, you know, I
- 25 have an article on, say, COVID drugs and kidney

Page 26

- 1 disease. Then, you know, it might be -- so there's
- 2 some distinction. It might be in the editorial
- 3 section.
- 4 It might be -- I think it's also --
- 5 original research carries -- at least for academic
- 6 promotion, it carries more weight. It's not that
- 7 educational publications are not important, but they
- 8 are distinct.
- 9 Q. So as I'm sure you can predict, we're going
- 10 to talk a lot about meta-analyses and pooled
- 11 analyses later today. Those you consider original
- 12 research, even though they're not collecting the
- 13 data originally.
- 14 A. Yes.
- 15 Q. Okay. So back to your CV. Have you
- 16 published any educational publications since 2019?
- 17 A. I'd have to go back and look at it. Don't
- 18 recall.
- 19 Q. If I said there were none listed there,
- 20 would you believe me?
- 21 MS. PARFITT: Objection. Form. If you
- 22 need to look, Doctor.
- A. That is correct.
- 24 Q. Okay. Next page, page 29, peer-reviewed
- 25 case reports. First of all, again, can you explain

- Page 2
- 1 look at some of my reports, some of them -- for 2 example, we describe the report of Wernicke --
- 3 W-e-r-n-i-c-k-e -- encephalopathy. Yeah. Case
- 4 reports can be informative in the -- but, obviously,
- 5 if it's a common disease, then they're not as
- 6 informative as other study designs.
  - Q. Would you agree with me that, holding the
- 8 disease at issue constant, a case report is less
- 9 informative than other study designs?
- 10 MS. PARFITT: Objection. Form.
- 11 Misstates the testimony.
- 12 A. I want to understand the question.
- 13 Q. Sure. Holding the disease at -- you
- 14 mentioned rare diseases versus common diseases. If
- 15 it's the same disease, is a case report less
- 16 informative than another type of literature?
- 17 MS. PARFITT: Objection. Form.
- 18 A. Yeah. If you had a more comprehensive
- 19 study design.
- Q. Let's look at correspondence on the next
- 21 page. Do you see any correspondence there since
- 22 2019?
- 23 A. No.
- Q. Okay. Can we flip back to 16? So these
- 25 are peer-reviewed original research publications.

Page 27

- 1 to me the difference between a case report and what
- 2 we might call a traditional peer-reviewed
- 3 publication?
- 4 A. Yeah. I mean, again, this is, you know --
- 5 these distinctions are more in our realm. In
- 6 academic world, you want to make a distinction on
- 7 the different type of scientific output that is
- 8 coming out of, you know, lab or a person's record.
- 9 You know, in terms of distinction, case
- 10 report is usually just one report that talks about,
- 11 say, something that's really important or novel that
- 12 gets across a point. So that's why it's in a
- 13 distinct section.
- 14 Q. It usually deals with one case?
- 15 A. Yeah. Usually. Sometimes case reports are
- 16 combined with case reports and reviews of the
- 17 literature. So, you know, they could be in a
- 18 different section.
- 19 Q. Are the results from case reports generally
- 20 considered less reliable than the results from what
- 21 we might call multicase literature?
- 22 MS. PARFITT: Objection. Form.
- A. You know, that goes to the question at
- 24 hand. Sometimes, you know, if the question is --
- 25 outcome is rare, usually, sometimes -- if you can

- 1 And I count 33 since your last deposition.
- 2 A. Yeah. I don't remember the exact time, but 3 yes.
- 4 MS. PARFITT: Why don't you take a look
- 5 at your CV, Doctor.
- 6 A. I'm going with 33. December '19, so.
- 7 Q. Do any of the publications listed since
- 8 January of 2019 address talc?
- 9 A. No.
- 10 Q. Okay. What about asbestos?
- 11 A. No.
- 12 Q. What about ovarian cancer?
- 13 A. No.
- 14 Q. Have you conducted any studies outside of
- 15 litigation related to ovarian cancer since 2019 that
- 16 are not listed here as publications?
- 17 A. No.
- 18 Q. Okay. Do you have any forthcoming
- 19 publications related to ovarian cancer?
- 20 A. No.
- 21 Q. Okay. Are you working on any non-
- 22 litigation research related to ovarian cancer
- 23 currently?
- 24 A. No.
- 25 Q. Okay. Have you submitted the substance of

Page 30	Page 32
1 your opinions in this case for peer review?	1 A. I don't.
2 A. No.	2 Q. Do you remember if it was more or less than
3 Q. Okay. Outside of the statements you've	3 \$30,000?
4 given in litigation, have you given any public	4 MS. PARFITT: Objection. Form.
5 statements concerning talc and ovarian cancer since	5 A. I don't recall.
6 2019?	6 Q. What about In re Tasigna Products Liability
7 MS. PARFITT: Objection. Form.	7 Litigation?
8 A. I've not spoken in the public, no.	8 A. Yeah. This was a recent litigation. That,
9 Q. Any statements about asbestos?	9 I recall. And I provided expert report and
10 A. No.	10 deposition that was admitted under Daubert recently.
11 Q. Okay. Let's look at page 13. These are	11 I recall that. Yeah.
12 presentations you've given?	12 Q. And what was the nature of your opinion in
13 A. Yeah. This is a team. I mean, I have been	13 that case?
14 on some. Others, I've presented. I'm not	14 A. Yeah. That Tasigna is causally related to
15 necessarily the first presenter.	15 the development of atherosclerosis and peripheral
16 Q. Understood. Fair to say, based on your	16 artery disease.
17 answer to the last question, that none of the	17 Q. What does the drug Tasigna do?
18 presentations since 2019 relate to talc or ovarian	18 A. It is an anticancer drug.
19 cancer?	19 Q. Okay.
20 A. No.	20 A. CML for chronic myeloid leukemia.
21 Q. Okay. Any forthcoming presentations	21 Q. Do you remember approximately how much yo
22 related to talc or ovarian cancer?	22 were paid in that case?
23 A. No.	23 MS. PARFITT: Objection. Form.
24 MR. MARTIN: Okay. Let's move to	24 A. I don't recall.
25 Exhibit 4.	25 Q. Okay.
	,
Page 31  (List of testimony, Exhibit 4, marked)	Page 33  1 A. But it was more than 30,000.
2 Q. This is Exhibit B to your expert report.	2 Q. Okay. There you go.
2 Q. This is Exhibit B to your expert report.	
3 Is this exhibit a complete list of the testimony	
3 Is this exhibit a complete list of the testimony 4 you've given in the last four years?	3 A. I can tell you.
4 you've given in the last four years?	<ul><li>3 A. I can tell you.</li><li>4 Q. Thank you. More than a hundred thousand?</li></ul>
<ul><li>4 you've given in the last four years?</li><li>5 A. That's as much as I can recall.</li></ul>	<ul> <li>3 A. I can tell you.</li> <li>4 Q. Thank you. More than a hundred thousand?</li> <li>5 MS. PARFITT: Objection. Form.</li> </ul>
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	Page 34		Page 36
1		1	MS. PARFITT: Objection. Misstates his
2	A. Yes.	2	testimony.
3	Q. Okay.	3	A. My opinion would be that talc causes
4		4	epithelial ovarian cancer. And your interpretation
5	Q. Have you submitted an expert report in any	5	could be that, since, you know, clear-cell is
6	of those cases?	6	epithelial ovarian cancer, then it increases that.
7	A. I don't recall. I mean, this is my listing	7	But my testimony is that talc causes epithelial.
8	of deposition, as far as I can recall.	8	Q. So your testimony is not broken down by
9	Q. Right. But, I mean, you'd agree with me	9	histological subtype of cancer.
10	that there are cases in which you may submit an	10	A. That is correct.
11	expert report. It may settle. You may never be	11	Q. Okay. And, again, just to be clear, it's
12	deposed.	12	related to both invasive and borderline cancer.
13	A. I don't recall that. May have. Yeah.	13	A. Yes. You know, all epithelial cancers.
14		14	Q. Have you done any outreach to any public
15	MR. MARTIN: Can we mark this as Exhibit	15	health organizations related to talc use and ovarian
16	5?	16	cancer?
17	(Supplemental expert report of Sonal	17	MS. PARFITT: Objection. Form.
18	Singh, M.D., M.P.H, Exhibit 5, marked)	18	A. No, I have not.
19	_	19	Q. Let's talk about the American College of
	your pile. We'll probably be referring back to this	l .	Gynecology. Would you agree it's generally a
1	several times. And this is your expert report in		reputable organization?
1	this case your supplemental expert report in this	22	MS. PARFITT: Objection. Form.
	case.	23	A. That is correct.
24		24	Q. Okay. Have you looked at any statements
25	have been asked to supplement my previous expert		made by the American College of Gynecology since
1			
	D 25		
1	Page 35		Page 37
1	report submitted on November 16, 2018 on whether the	1	Page 37 your last deposition?
2	report submitted on November 16, 2018 on whether the genital use of talcum powder products i.e.,	1 2	Page 37 your last deposition? A. I don't recall.
2 3	report submitted on November 16, 2018 on whether the genital use of talcum powder products i.e., Johnson's Baby Powder and Shower to Shower are	1 2 3	Page 37 your last deposition? A. I don't recall. Q. Okay. Are you aware that they have updated
2 3 4	report submitted on November 16, 2018 on whether the genital use of talcum powder products i.e.,  Johnson's Baby Powder and Shower to Shower are causally related to an increased risk of ovarian	1 2 3 4	Page 37 your last deposition? A. I don't recall. Q. Okay. Are you aware that they have updated their Website's "frequently asked questions" on
2 3 4 5	report submitted on November 16, 2018 on whether the genital use of talcum powder products i.e.,  Johnson's Baby Powder and Shower to Shower are causally related to an increased risk of ovarian cancer." Are you offering an opinion related to any	1 2 3 4 5	Page 37 your last deposition? A. I don't recall. Q. Okay. Are you aware that they have updated their Website's "frequently asked questions" on ovarian cancer since your last deposition?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	report submitted on November 16, 2018 on whether the genital use of talcum powder products i.e., Johnson's Baby Powder and Shower to Shower are causally related to an increased risk of ovarian cancer." Are you offering an opinion related to any non-ovarian types of cancer?  A. No. Q. Okay. So not mesothelioma? A. No. Q. Not uterine cancer? A. No. Q. Okay. Are you offering an opinion related to all ovarian cancers? A. Epithelial. Q. Epithelial ovarian cancer. Okay. Thank you.  Does the histological subtype of epithelial ovarian cancer matter?  MS. PARFITT: Objection. Form. A. My work and opinions in this case are focused on epithelial ovarian cancer. To the extent that histologic types, you know, are included within	1 2 3 4 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Page 37 your last deposition? A. I don't recall. Q. Okay. Are you aware that they have updated their Website's "frequently asked questions" on ovarian cancer since your last deposition? MS. PARFITT: Objection. Just testified he had not looked at it. A. Yeah. I don't recall. I mean, if you show me, I can Q. Okay. Well, we can do that. MR. MARTIN: This will be Exhibit 6. (ACOG printout, Exhibit 6, marked) Q. Can we turn to they're not paginated but the second page of this document. A. Sure. Q. Actually, I apologize. Let's turn back to let's start with page let's start with the final page of substantive text. Do you see that it's it says last reviewed November 2021 and last updated May 2022? A. That is correct. Q. Okay. Now we can turn to the second page.

Pageib. 21	2781
Page 38	Page 40
1 Q. I'll give you a minute.	1 A. I don't recall. But if I said that, you
2 MS. PARFITT: Thank you.	2 know, we can look at it, and
3 A. Yes.	3 Q. We don't need to look at it. Do you
4 Q. Okay. Thank you. Agree with me that	4 currently counsel your female patients to avoid
5 talcum powder use genital talcum powder use is	5 genital talcum powder use?
6 not listed there?	6 A. I think, you know, if particularly as it
7 A. That is correct.	7 relates to ovarian cancer, yes.
8 Q. Do you disagree with ACOG's decision not to	8 Q. Yes. Do you do that only if they ask, or
9 list genital talcum powder use as a risk factor for	9 is that something you affirmatively say to them?
10 ovarian cancer?	10 MS. PARFITT: Objection. Form.
11 A. Yes.	11 A. I mean, you know, there's so much going on
12 Q. You do. Okay. Have you told anyone at the	12 at a clinic visit that, you know, I'm not asking
13 organization that?	13 everyone about but when, you know, the decision
14 A. No.	14 goes about modifiable risk factors, I do ask.
15 Q. Okay.	15 Q. Is it fair to say it's not one of your
16 A. I don't I'm not an OB-GYN person.	16 highest priorities in an ordinary patient visit?
17 Q. Understood. Let's flip a few pages forward	17 MS. PARFITT: Objection. Form.
18 to "reducing risk." Do you see that section?	18 A. So it's, you know, you for example, I'll
19 A. Yes.	19 use example of lung cancer. You know, you see a
20 Q. Okay. And can you just take a second to	20 patient or who is at risk. You're talking about
21 review that section?	21 smoking. It's modifiable. You know, the risks for
22 A. Yes.	22 family histories are higher. But then that's not
23 Q. Okay. Thank you. Agree that there are	23 modifiable. You start thinking about weight
24 some lifestyle recommendations there, such as using	24 reduction, things that are modifiable.
25 hormonal birth control pills?	25 Q. Do you believe that the risk of ovarian
Page 39	Page 41
1 A. Yes.	1 cancer associated with talc use is comparable to the
2 Q. Okay. But, again, agree there's no	2 risk of lung cancer associated with smoking?
3 recommendation to stop using talcum powder?	3 MS. PARFITT: Objection.
4 A. Yes. But there's no recommendation to lose	4 A. No. I was just using that as an example to
5 weight as well. So it's not a full, comprehensive	5 explain how one discusses modifiable risk factors.
6 list of recommendations. Similarly, the risk	6 Q. I understand. It wasn't meant to be a
7 factors don't capture all the risk factors, such as	7 gotcha question. It was just a question.
8 height (verbatim). And so, you know, there's other	8 MR. MARTIN: Can we have this marked as
9 things smoking, we don't have it in the so	9 well? Luis, this is not Tab 7. This is Tab 8, just
10 it's not a comprehensive list. Obviously does not	10 if you're following along. This is the PDQ. I'm
11 include talc but also does not include other things.	11 sorry, Luis. It's actually Tab 9.
12 Q. Do you think this section should be more	MR. CHU: Okay. Got it. Thanks.
13 comprehensive?	13 MR. MARTIN: But it's Exhibit 7 here at
14 A. Exactly.	14 the deposition.
15 Q. Okay.  MS. DADEITT: "This section" magning the	15 (National Cancer Institute PDQ printout,
16 MS. PARFITT: "This section" meaning the 17 risk factors and	16 Exhibit 7, marked) 17 THE WITNESS: Can we take a break after
18 MR. MARTIN: I apologize.	18 this question?

MR. MARTIN: Sure. If you'd like, we

MR. MARTIN: Let's go off the record.

MR. MARTIN: Back on the record.

Q. Do you remember talking about the National

THE WITNESS: Yeah.

(A break was taken)

19

21

22

23

24

25

20 can take a break now.

25 testimony?

20 comprehensive?

A. I agree.

21

Q. Do you think this Website should be more

Q. Okay. At your last deposition, I believe

24 avoid genital talcum powder use. Do you recall that

23 you said that you counsel your female patients to

Page 42

- 1 Cancer Institute PDQ at your previous deposition?
- 2 A. I don't recall, but I have seen this
- 3 document that you presented.
- Q. Okay. Let's look at -- let's actually look
- 5 at your deposition, which I can mark as whatever the 6 next exhibit is.
- 7 (January 16, 2019 transcript of Sonal
- 8 Singh, M.D., M.P.H, Exhibit 8, marked)
- 9 Q. Can we look at the beginning of page 94 of
- 10 your deposition, traditional page 94, which is page
- 11 25 of the mini document?
- MS. PARFITT: He's talking about the
- 13 actual page number.
- 14 A. Yeah.
- 15 Q. Begins "All right. This document." "This
- 16 document that we're looking at from the National
- 17 Cancer Institute, Exhibit 15, was updated in January
- 18 of 2019." And your answer is "Yeah. But it doesn't
- 19 mean the review is updated because it has no recent
- 20 citations of studies that have been conducted."
- 21 So fair to say that one of your criticisms
- 22 of the PDQ at your last deposition was whether it
- 23 was updated based on the most recent research?
- 24 A. That is correct.
- Q. Okay. Let's go back to the PDQ -- the new

- Page 44
- 1 A. Yeah. 13, 14. So the question is "What is 2 the methodology they've applied," you know, before
- 3 concluding anything in looking at, you know, all the
- 4 ratios, study designs. So yes, obviously, if it is
- 5 comprehensive, then yes, you know, it is relevant.
- 6 Q. So let's look at the talc section, which is
- 7 a few pages back, not that many pages back. If we
- 8 can look at the first short paragraph.
- 9 You agree that PDQ still believes the data
- 10 are inadequate to support an association between
- 11 perineal talc exposure --
- MS. PARFITT: Objection. Form.
- 13 Q. -- and increased risk of ovarian cancer?
- 14 MS. PARFITT: Objection. Form.
- 15 Misstates testimony.
- 16 A. Right. That is what PDQ states. I don't
- 17 agree with their statement there, but that's what
- 18 the PDQ --
- 19 Q. Understood. Okay. Can we look at the
- 20 reference list?
- 21 A. Sure.
- Q. Particularly 10 and 11 on the reference
- 23 list. Can you read what 10 and 11 are for me?
- 24 A. Yeah. The meta-analysis and the pooled
- 25 analysis by O'Brien -- meta-analysis by Dr. Woolen
- Page 43
- 1 PDQ that I just circulated.
- 2 A. 7?
- 3 Q. Yeah. There's a lot to keep track of.
- 4 A. Okay
- 5 Q. Let's turn to the final page right at the
- 6 bottom.7 MS. PARFITT: Zack, if you could kind of
- 8 give us a category.
- 9 Q. It's the last page of the document. It's 10 not a category. It's, like, "Disclaimer," "Contact
- 11 us." that stuff.
- MS. PARFITT: Perfect. Thank you.
- 13 Q. Unfortunately, none of these Web pages are
- 14 paginated, which makes it difficult. But you see
- 15 "Updated October 16, 2023"?
- 16 A. That is correct.
- 17 Q. Okay. But I recall that one of your
- 18 criticisms last time was that, even if it says it's
- 19 been updated recently, it doesn't necessarily take
- 20 into account all the scholarship. Was that correct?
- 21 A. Yeah. And that is sort of the methodology
- 22 applied, what are the studies they have evaluated.
- 23 And so even here, we can see that they have 13
- 24 references in the talc section.
- Q. 14, I believe. But yes, I see that.

- 1 and the pooled analysis by O'Brien.
- Q. Do you agree that those are two of the most
- 3 up-to-date studies on the relationship between talc
- 4 and ovarian cancer?
- 5 A. They are some of the most up-to-date, not
- 6 necessarily the most updated. I mean, you know,
- 7 there's meta-analysis by Penninkilampi. There's
- 8 meta-analysis by Health Canada. So, you know,
- 9 there's a causality assessment.
- 10 So there, you know -- there's all these
- 11 OCAC consortium studies. There's OCWAA consortium
- 12 studies. So there's many other studies that they
- 13 could have looked at.
- 14 Q. Understood. Do you know of a meta-analysis
- 15 more recent than Woolen's meta-analysis?
- A. Yeah. But, you know, Woolen's meta-
- 17 analysis is relevant. But it is relevant to the
- 18 frequency. But, you know, the overall body of
- 19 evidence -- case and control and cohort -- was Taher
- 20 and Penninkilampi.
- 21 Q. Understood. Can you try to answer the
- 22 question I asked, though, which is are you aware of
- 23 a meta-analysis that's more recent than the Woolen
- 24 meta-analysis?
- 25 MS. PARFITT: Objection. Asked and

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Page 46 1 answered.

- 2 A. I don't follow the dates. I mean, whatever
- 3 is in my report includes the relevant analysis from 4 the date of previous report. There may be some --
- 5 you know, whether you're referring to Lynch, which
- 6 is more updated or -- I don't know the exact date
- 1 don't know the exact dat
- 7 when it was published. But it is in my report.
- 8 Q. Okay. You'd agree that Lynch also
- 9 concludes that talc does not cause ovarian cancer;
- 10 is that correct?
- 11 MS. PARFITT: Objection. Form.
- 12 A. Yeah. Lynch concludes -- to be more
- 13 precise, Lynch does not conduct a meta-analysis.
- 14 They're only a systematic review. But yes, the
- 15 inference is that it does not. And we can discuss
- 16 why it concludes that and what are my concerns about 16
- 17 it.
- 18 Q. I think we might get to that this
- 19 afternoon.
- 20 A. Okay.
- 21 Q. On O'Brien, are you aware of any pooled
- 22 analysis of cohort studies more recent than O'Brien?
- 23 MS. PARFITT: Objection. Form. Asked 24 and answered.
- 25 A. Yeah, there are. I mean, the OCAC

- 1 A. That is correct.
  - 2 Q. Okay. Do you think it's generally a
  - 3 reputable organization?
  - 4 A. It is a reputable organization, not
  - 5 "generally."
  - 6 Q. Okay. Are you aware that they put out a
  - 7 "Cancer Facts & Figures" document every year?
  - A. Yes. I refer to it, you know, at times.
  - 9 Q. And what we have in front of us is the one
  - 10 from 2024. This document is long, but it's
  - 11 mercifully paginated this time. Can we turn to
  - 12 page 22?
  - 13 A. Yes.
  - 14 Q. Okay. Can you review the two paragraphs
  - 15 there on page 22 under "Ovary"?
  - 16 A. Yes.
  - 17 Q. Okay. Do you agree with what it says here,
  - 18 that the incidence rate has declined by somewhere
  - 19 between 1 and 3 percent a year over the last 30
  - 20 years or so?
  - 21 A. Yes.
  - Q. Okay. Do you agree that that can be
  - 23 attributed to increased oral contraceptive use and
  - 24 decreased postmenopausal hormone therapy?
  - 25 MS. PARFITT: Objection. Form.

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1 consortium, the OCWAA consortium. Not of cohort

- 2 studies but case control studies.
- 3 O. The answer with cohort studies is no?
- 4 A. No.
- 5 Q. Okay. So would it be fair to say that you
- 6 don't believe that the references cited by the PDQ
- 7 are comprehensive?
- 8 A. That is correct.
- 9 Q. Okay. Separate from whether they are
- 10 comprehensive, do you believe they're up to date?
- 11 MS. PARFITT: Objection. Form.
- 12 A. I mean, if they're not comprehensive enough
- 13 and they don't consider the whole body of evidence
- 14 and don't do a causality assessment, as I have done,
- 15 I don't know -- when they say "up to date," I really
- 16 don't know, you know, did they consider everything
- 17 and then decide to exclude Lynch or for some reason
- 18 others? It's unclear why they excluded and included
- 19 certain studies.
- MR. MARTIN: Okay. Next exhibit, Luis,
- 21 this is Tab 11 in our binders. This is 9.
- 22 (American Cancer Society printout,
- 23 Exhibit 9, marked)
- 24 Q. You're familiar with the American Cancer
- 25 Society, I assume.

- $$\operatorname{Page}\,49$$  A. Those are one of the causes. There could
- 2 be others. I mean, I think one of the others is,
- 3 you know, better ascertainment. We are becoming
- 4 much more aware of it, so.
- 5 Q. Can I ask you why better ascertainment
- 6 would influence -- would impact the case rate?
- 7 A. Yeah. I mean, we are diagnosing it more,
- 8 but the incident rate is declining.
- 9 Q. Okay. Can we turn to page 23, which is the
- 10 next page. And can you review the paragraph for
- 11 "Risk factors"?
- 12 A. Sure. Yes.
- 13 Q. Okay. So the first sentence there, "The
- 14 most important risk factor other than age is family
- 15 history of breast or ovarian cancer." Agree with
- 16 the implication that the most important risk factor
- 17 of all is age?
- 18 MS. PARFITT: Objection. Misstates
- 19 testimony.
- 20 A. I mean, I don't know if I would say -- the
- 21 most important other than age, they're saying, is
- 22 breast or family history of cancer.
- 23 Q. Right. Would you agree that, by saying
- 24 "other than age," that implies that age is the
- 25 number 1 most important?

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- 1 MS. PARFITT: Objection. Form.
- 2 A. Okay. Yeah.
- 3 Q. Okay. And would you agree that the next
- 4 most important is history of breast or -- family
- 5 history of breast or ovarian cancer?
- 6 MS. PARFITT: Objection. Misstates his 7 testimony.
- 8 A. Yes.
- 9 Q. Okay. Also lists a number of protective
- 10 and additional risk factors below there.
- 11 A. That is correct.
- 12 Q. Okay. And the last sentence, "The weight
- 13 of the evidence does not support an association
- 14 between ovarian cancer and genital exposure to talc-
- 15 based powder." Assume you disagree with the
- 16 American Cancer Society about this.
- 17 A. Yes. Again, you know, partly because I
- 18 don't see any references in how they came to that
- 19 weight-of-evidence conclusion. Did they do a
- 20 causality assessment? What are the studies that
- 21 they evaluated to come to that conclusion?
- Q. Have you ever told anyone at the American
- 23 Cancer Society you disagree with them?
- MS. PARFITT: Objection. Form.
- 25 A. Many times with CDC, with the American --

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  Q. Have you read the order that excluded your
  - 2 opinion?
  - 3 A. I haven't read the full order, but I did
  - 4 read the portions of it relevant to my -- yeah.
  - 5 Q. Makes sense.
  - 6 MR. MARTIN: Could I have this -- which,
  - 7 Luis, is Tab 13 in our binders -- marked as
  - 8 Exhibit 10?
  - 9 (Order from Court in Viagra case,
  - 10 Exhibit 10, marked)
  - 11 Q. Let's turn to federal supplement page 796,
  - 12 97, which is WestLaw page 14.
  - 13 A. Yes.
  - 14 Q. Last sentence of the first paragraph in the
  - 15 second column, "As Li 2014 was one of the smallest
  - 16 studies and its results have not been duplicated,
  - 17 Dr. Singh has not provided a persuasive reason to
  - 18 rely more heavily on it."
  - 19 A. Where?
  - Q. Last sentence of the first paragraph on the
  - 21 second column. So agree that the Court excluded
  - 22 your opinion, in part, for placing undue emphasis on
  - 23 a smaller study?
  - 24 A. That is correct.
  - 25 MS. PARFITT: Objection. Form.

- 1 lot of people disagreed with the CDC in COVID. So
- 2 yeah.
- 3 Q. I understand you disagree. I'm asking if
- 4 you've ever told anyone at the American Cancer
- 5 Society that.
- 6 MS. PARFITT: Objection.
- 7 A. About this particular --
- 8 Q. About this particular issue.
- 9 A. No.
- 10 Q. Okay. You can put that aside. Do you
- 11 recall giving an expert opinion in In re Viagra?
- 12 A. Yes.
- 13 Q. Okay. Did you testify in that case?
- 14 A. That is correct.
- 15 Q. Okay. I assume it wasn't in the last four
- 16 years, though. That's why it wasn't on the list we
- 17 went over earlier today?
- 18 A. That's correct. I think it was in my
- 19 previous list.
- 20 Q. Okay. Understood.
- 21 A. If I recall, I mean, it was in my previous.
- Q. Understood. Are you aware that, in 2020
- 23 after your most recent deposition, your opinion was
- 24 excluded in that case?
- 25 A. I am aware.

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  Q. Okay. Do you believe you've done that in

  this case?
- 3 A. No. I mean, there's -- the evidence has
- 4 been, you know -- that was one study. I mean, here
- 5 we've had, what, four decades of -- not four. I
- 6 don't know the exact time -- but several decades and
- 7 several case control studies and, you know, overall
- 8 body of evidence that provides for a causal opinion.
- 9 And I've not emphasized one study as opposed to
- 10 other, suggesting that, well, Li is, you know --11 I've looked at the cumulative body of evidence.
- 11 1 ve looked at the cumulative body of evidence
- 12 Q. You do weight some studies more heavily
- 13 than others?
- 14 A. Yeah. Strengths and limitations. Exactly.
- 15 Q. Can we go back to the end of the previous
- 16 column?
- 17 A. Which is on --
- 18 Q. It's the same page, previous column here,
- 19 "At the hearing Dr. Singh."
- 20 A. Yeah.
- 21 Q. "At the hearing, Dr. Singh candidly
- 22 admitted that the Bradford Hill criteria are
- 23 susceptible to an outcome-driven analysis, though he
- 24 contends he did not take such an approach here." Do
- 25 you still agree that the Bradford Hill criteria are

Page 54 Page 56 1 susceptible to an outcome-driven analysis? 1 relationship -- the particular association that 2 MS. PARFITT: Objection. Form. 2 you're looking at? 3 3 A. That is correct. A. Exactly. 4 Q. Still agree that you're not taking that 4 Q. Okay. How do you make that decision when 5 approach here? 5 you're looking at an association? A. No. A. So you'd have to still rank them. But, you 7 Q. Okay. Next sentence, "Dr. Singh testified 7 know, you're finally making a causal determination. 8 that the criteria are not ranked in any order of 8 And whoever is, they'd have to either make a 9 importance, which is contrary to the position he has 9 rational argument that biologic, say -- I'm just 10 taken in prior litigation and contrary to how it 10 using example of biologic plausibility -- is the --11 appears they are usually applied." 11 is, you know, driving the causal assessment. 12 Do you believe there's any particular order 12 Q. Is that decision a subjective process, 13 of importance associated with the Bradford Hill 13 objective process, or partially subjective and 14 criteria? 14 partially objective? 15 A. So, I mean, this sort of comes out of 15 MS. PARFITT: Just objection. Form. 16 Dr. Bradford Hill's paper, which, prior to getting 16 A. No. Yeah --17 into the viewpoints, not even criteria -- so I, Q. Can I redo the question? 17 18 again, have -- it says "ranked in order of 18 A. I can answer that. Yeah. 19 importance." So that's sort of his -- so when we 19 Q. Is that a subjective or objective process? 20 use his viewpoints, you know, that's what his 20 A. So it, you know -- there is no quantitative 21 assessment was and -- yeah. 21 way to weigh the Bradford Hill viewpoints. He never 22 Q. So sorry. Just to make a clear record. Do 22 stated it that way, that you give 10 points to 23 you agree -- I think there's two questions here. 23 strength, 2 points to consistency, and 1 point to Do you agree, first, that Dr. Hill was --24 biologic plausibility. 25 ranked those viewpoints in order of importance? 25 It is not a subjective. I would say it is Page 55 Page 57 1 MS. PARFITT: Objection. Form. 1 a scientific opinion based on, most of the time, 2 A. I mean, the -- his article talks about 2 there is quantitative data either to support or 3 these viewpoints in order of importance. 3 refute that opinion. In certain cases, there is no 4 evidence. Q. Okay. Do you, Dr. Singh, believe that they 5 can be ranked in order of importance? MR. MARTIN: Can we have this marked as A. They can. 6 the next exhibit? This is, Luis, Tab 15 in our 7 Q. Okay. Which would you find to be the most 7 binders. It's Exhibit 11. (February 2, 2023 transcript of Sonal 8 important? A. I mean, just go by, you know, strength of 9 Singh, M.D., M.P.H, Exhibit 11, marked) 10 association. I have to look at the list. 10 Q. This is the deposition in the Tasigna case Q. Understood. Do you believe that the same 11 we talked about. 12 -- whether you want to call them viewpoints or 12 A. This is the recent deposition or --13 criteria, are most important in every case? Or do 13 Q. Let me look at the date on it. 14 14 you believe that -- you know what? Let's ignore MR. TISI: Just a question. Is this 15 that question. 15 covered by any kind of confidentiality order? I'm 16 not sure we would have access to it. Do you know --16 A. So I can clarify, since you asked that. 17 Q. Yeah. 17 THE WITNESS: No. This was admitted

15 (Pages 54 - 57)

19

21

23

25

18 under Daubert.

20 question.

24 either.

MR. MARTIN: No. I understand the

THE WITNESS: I don't have access to it

MR. MARTIN: I understand. I don't -- I

MR. TISI: If it's covered by a

22 confidentiality order, we didn't --

25

24 contribute to causation.

A. So while he listed the viewpoints, ranked

20 necessarily will not be important in each case, you

21 know, taking it out of talc or -- you know, could be

22 X associated with Y. In some cases, consistently

19 them in order of importance, each criteria

23 and biologic plausibility may be enough to

Q. So it depends on the particular

1	Page 58	1	Page 60
	don't believe so. But can we go off the record for		whether you still believe that they're all
	a second and confirm that?		important, you have to apply them qualitatively?
3	` ′	3	MS. PARFITT: Actually, that misstates
4			his testimony.
	follow up on the issue that was raised before, my	5	A. Yeah. And you have to look at the report.
	understanding now is that we received these from a		I mean, all of them were applied, and all of them
	public records source. So I'm comfortable using		are important. But, obviously, in certain contexts,
	them. So I'll redistribute these, which, again, are		some of them may be more relevant than others.
	the depositions you gave in the Tasigna I'm sure	9	So I don't see any you have to look at
11	I'm pronouncing that wrong MDL.  THE WITNESS: That's correct.		the report. I mean, you can't look at this document in isolation. We should bring that you know, if
12			you pull that off, you could have I'm sure you
13	5 ,		have the report.
14		14	Q. I do.
15		15	A. Let's look at the report and see.
16		16	Q. No. Again, it's not intended to be a
17	, , ,		gotcha question. I'm trying to understand the scope
18	MR. MARTIN: No problem. It does look		of your opinion.
19	-	19	A. Yeah. You have to look at all of that.
20	·		And then, you know, you have to decide, you know,
21			which in certain cases for example, dose
22			response. It may not apply. If a drug is given at
23	MR. TISI: So these were not in the		one dose, how will that apply? I mean, you look at
24			it, but it may not be relevant.
25	MR. MARTIN: Correct. I was just trying	25	Q. If a drug is given in multiple doses, do
	, , ,		
1	Page 59 to bring attention to myself and to Dr. Singh.	1	Page 61 you believe dose response is an
2	MR. TISI: I just want to understand	2	A. Yes.
	what the highlighting's for.	3	Q important criteria?
4	THE WITNESS: Just so you know, I have	4	A. Yes.
	not reviewed this.	5	Q. Can we look back at your report in this
6	MR. MARTIN: Understood. I'm just going		case?
7	to touch on it very briefly.	7	MS. PARFITT: Just for the record, it's
8	THE WITNESS: Sure.	8	Exhibit No. 5.
9	Q. So if you can turn to deposition page 283,	9	A. 5.
10	which is page 72 of the document. So if you can	10	Q. Okay. Does the November 2013 (verbatim)
	review where the highlighting begins down to the end	11	
	of the page.		give in this case that are not included in your
13	MS. PARFITT: That would be Line 11 down		previous 2019 report?
14	to 25?	14	A. 2023, to correct. It was not 2013.
15	MR. MARTIN: Correct.	15	Q. Thank you for fixing that.
16	MS. PARFITT: Continuing onto the top	16	A. No. I think, you know, these are linked
17	of.	17	reports. I mean, it's not that I'm I think I'm
18	MR. MARTIN: You do not need to continue	18	providing testimony on the update between the 19th
19	onto the top of the page.	19	and 23rd in this report. Maybe you can restate the
20	*	20	question. I'll try to answer it.
21	Q. Yes. The question and the answer to that.	21	Q. Understood.
22	A. The answers is "Temporality is important,	22	MR. TISI: You said "the 19th."
23	strength of association, consistency, plausible"	23	MS. PARFITT: Let's redo dates here.
	1 11 11 0 1 77 1		AD MADEEN W
	now you're listing all of them. Yeah.  Q. So my question with this document is	<ul><li>24</li><li>25</li></ul>	MR. MARTIN: Yes.  Q. Do the 2018 report and 2023 report together

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- 1 define the full scope of the opinions you plan to 2 offer?
- 3 A. That is correct.
- 4 Q. Okay.
- 5 A. Sorry about dates.
- 6 Q. No. Understood. Can we turn to page 4 of
- 7 the 2023 report. So you say in page 4 that you use
- 8 the weight-of-the-evidence approach in examining the
- 9 causal relationship. Can you define for me what you
- 10 mean by weight-of-the-evidence approach?
- 11 A. The weight of evidence is, you know,
- 12 gathering all the relevant body of evidence to the
- 13 specific scenario and the cumulative body of
- 14 scientific and medical evidence for a systematic
- 15 review based on animal studies, in vitro studies,
- 16 human studies -- including epidemiologic studies --
- 17 and then -- including published, most of the time,
- 18 you know, peer-reviewed documents, other documents 18
- 19 which -- then examining them for whether they are
- 20 relevant and reliable to the present -- the context
- 21 and then examining them through the lens of the
- 22 Bradford Hill viewpoints.
- And, obviously, these are -- there is no
- 24 quantitative way to say that strength of evidence
- 25 gets 7 points and, you know, biologic plausibility
  - Page 63
- 1 gets 1 and dose response gets 2.
- Q. To the extent you draw causal conclusions
- 3 in your professional work, is this the same
- 4 methodology that you use in your professional work?
- 5 A. So my professional work is clinical; right?
- 6 So I see patients. So we use the differential
- 7 diagnosis as -- we don't necessarily -- we don't
- 8 have to make causal determinations when I see 9 patients.
- 10 Q. Understood. But I guess I was referring to
- 11 your published academic work. To the extent you
- 12 draw causal conclusions in your publications, is it
- 13 the same methodology that you use?
- 14 A. Yeah. I mean, if you are going to draw
- 15 causal conclusion, you would use -- I mean, Health
- 16 Canada has used the same approach. They've used a
- 17 weight-of-evidence approach. So they may have
- 18 defined it differently, but they have used a weight-
- 19 of-evidence approach.
- There are other approaches. I mean, you
- 21 know, it's not, like, the only approach. I'm being
- 22 transparent about what I've gathered, what I've
- 23 used, and how I rate it. I've rated certain
- 24 viewpoints more than others. And that's, you know,
- 25 that's my approach.

- 1 MS. PARFITT: Zack, I'm not sure exactly
  - 2 where you're going. I've giving you a little
  - 3 runway. I think, you know, from 2018, we talked
  - 4 quite a bit about how to make a causal inference
  - 5 using Bradford Hill criteria.
    - MR. MARTIN: Understood.
  - 7 MS. PARFITT: So, again, giving you some 8 pretext but --
  - 9 MR. MARTIN: Understood. Understood.
  - 10 Yeah. I don't want to rehash things we've already
  - 1 done

17

- MS. PARFITT: Right. I'm looking at his
- 13 prior deposition, so.
- Q. Do you believe the methodology you used in
- 15 this 2023 report is the same as the methodology that
- 16 Health Canada used in their report?
  - MS. PARFITT: Objection. Form.
  - A. In general, yes. I mean, I'm not -- you
- 19 know, I didn't do exactly the same thing. I
- 20 actually relied on Health Canada so I didn't have to
- 21 redo what they had to do. So in a lot -- in the
- 22 majority of, you know, bodies of evidence that they
- 23 appraised, you know, they appraised, you know, the
- 24 O'Brien study. They appraised a lot of the
- 25 mechanistic studies. So I relied on them.
- Page 65
- But their -- in terms of assessment, yes.
- 2 I, you know -- to my best knowledge, I was, you
- 3 know, applying the weight-of-evidence approach.
- 4 Q. You mentioned that you conducted a Bradford
- 5 Hill analysis in your 2023 report. You also
- 6 conducted one in your 2018 report. And your opinion
- 7 in 2018 was that the evidence was sufficient to
- 8 reach a causal conclusion. Why did you feel the
- $9\,$  need to conduct an additional Bradford Hill analysis
- 10 in 2023?
- 11 MS. PARFITT: Objection. Form.
- 12 A. So evidence was sufficient to reach a
- 13 causal conclusion at that time. But when I was
- 14 asked to update my report, I -- this is not
- 15 something of my own choosing. I was asked to do it.
- And so I could not just look at the body of
- 17 evidence and, you know, at the end of -- say "Well,
- 17 evidence and, you know, at the end of Bay Wel
- 18 you know, I agree with what I said then." So I had
- 19 to look at it through the lens of what is known in
- 20 the previous time, what is here. So I would have to
- 21 do the Bradford Hill analysis.
- Q. So is it fair to say that your opinion is
- 23 that, given the intervening new science, you felt it
- 24 important to do a new Bradford Hill analysis?
- 25 MS. PARFITT: Objection. Misstates his

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1 testimony.

- A. No. I think that whatever I evaluated from
- 3 2019 -- let's get the dates right -- until, you
- 4 know -- 2018 was my report -- then 2023, this new
- 5 search, I felt that, since I was going to provide a
- 6 causal opinion, updated causal opinion, while at
- 7 that time, you know, the opinion, you know, body of
- 8 evidence was sufficient -- if you're looking at a
- 9 body of evidence and, again, arriving at a causal
- 10 opinion -- then, you know, I had to be transparent
- 11 in my assessment. I could not, for example, end at
- 12 page 2 -- 17 and just give you a one-line
- 13 conclusion.
- Q. Can we look at page --14
- 15 A. This is my report; right?
- Q. Yes, it is. 16
- 17 A. Which page is it?
- Q. Well, I guess I'll ask a general question.
- 19 You can look through your report.
- 20 Do you agree that, in your 2023 report, you
- 21 assigned less weight to the factor of dose response
- 22 or biological gradient than some of the other
- 23 factors?
- 24 A. Let me just look at the wording that I
- 25 used.

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- Q. Yes. It's on page 21. 1
- 2 A. Yes.
- 3 Q. Okay. And can you point to any literature
- 4 suggesting that it's appropriate to weight the dose
- 5 response factor less than the other factors?
- MS. PARFITT: Objection. Form.
- 7 A. So it is not that -- it is -- I'm trying to
- 8 be transparent on -- for example, there's no
- 9 literature to suggest that experiments should be --
- 10 you're not going to get experimental data on this
- 11 question.
- 12 So, of course, I weighed -- it's my
- 13 weighting of the factors. Does not mean that those
- 14 dose response is not -- I evaluated dose response.
- 15 There were some -- you know, several studies which
- 16 provided dose response; some studies did not.
- 17 So I weighed -- so my -- I think I have to
- 18 be clear that my assessment -- the factors driving
- 19 my assessment are consistency and strength of
- 20 evidence, temporality, plausibility, and coherence.
- So dose response is also there but to a
- 22 lesser -- so it's my assessment of the viewpoints.
- 23 It's not necessarily, you know -- you're right.
- 24 There's not literature suggesting that dose response
- 25 should not be used in assessment.

Q. All right. Thank you. Are you offering

- 2 the opinion that cosmetic talcum powder contains 3 asbestos?
- A. So my causality opinion's not predicated on 4
- 5 presence of asbestos in talc. But as was noted in
- 6 my previous report and in my present report, I'm
- 7 aware of studies that provide evidence that talc may
- 8 contain asbestos.
- Q. Which studies are you relying on for that?
- 10 MS. PARFITT: I guess I'll give a bit of
- 11 leeway. Again, this area was examined at his prior
- 12 deposition, 2019.
- 13 THE WITNESS: Let me answer.
- 14 MS. PARFITT: I'm giving you context --
- 15 I'm giving you a little leeway. Go ahead,
- 16 Dr. Singh.
- 17 THE WITNESS: I have to find it now.
- 18 MS. PARFITT: Take your time.
- 19 Q. It's on page 13, I think.
- 20 A. Let's see. I just want to be precise by my
- 21 language. Yeah. So the studies I'm relying on are
- 22 the FDA testing, testing by -- that was cited in the
- 23 previous report, I think, Johnson & Johnson testing,
- 24 and then obviously the testing by Dr. Longo and
- 25 Rigler and now, subsequent to this, the EPA

- 1 conclusions about the presence of asbestos in talc. 2
- Again, I'm not a mineralogist, but several 3 lines of evidence -- in fact, even epidemiologists
- 4 have at least acknowledged and are starting to
- 5 interpret the evidence that -- for example, O'Brien
- 6 in a recent paper on fibroids said that, you know,
- 7 talc may be contaminated with asbestos.
- O. Let's break that down --8
- 9 A. Sure.
- 10 Q. -- one by one. You mentioned an EPA study
- 11 that you said was subsequent to -- do you mean
- 12 subsequent to your report or subsequent to your
- 13 previous deposition?
- 14 A. No. Subsequent to my report. Like, this
- 15 EPA -- not study. It's an EPA ruling.
- MR. MARTIN: Was that in the materials 16
- 17 that you gave us Monday?
- 18 MS. PARFITT: Yes, it was.
  - THE WITNESS: That's the EPA ruling. I
- 20 mean, it just came out -- what -- a couple of weeks
- 21 ago?

- 22 MS. PARFITT: Yes.
- 23 THE WITNESS: But we have to bring it
- 24 out. I don't remember.
- 25 MR. TISI: If you want a copy, I can get

PageID: 212789 Page 70 Page 72 A. And I will not be testifying to testing of 1 a copy. 2 talc and presence. 2 MR. MARTIN: If you have one handy, I'll 3 3 take a quick look at it and review it over the Q. Understood. 4 A. And quantity of -- sorry -- quantity of 4 break. 5 asbestos and --MR. TISI: Sure. Q. Understood. Have you personally reviewed THE WITNESS: Yeah. This was not 6 6 7 the testing done by Drs. Longo and Rigler? 7 included in my citations. MS. PARFITT: For the record, it was, in 8 A. Yes. I reviewed the report. 9 9 fact, provided in the Dropbox, just for the record. Q. You reviewed the report? 10 And we will give you a copy. 10 A. Yeah. I -- you know, I reviewed the 11 methods. And to the extent I can understand it, I MR. TISI: I'd appreciate if you are 11 12 understood it. But I'm not expert in that area. 12 able to give it back because it's my only copy. 13 MR. MARTIN: No problem. I can probably Q. Have you reviewed any testing -- asbestos 14 testing performed by defense experts? 14 get it from the Dropbox. 15 A. Yeah. I've seen their -- I don't know if 15 MR. TISI: Can I just check something, 16 it's exhibits. I don't know if I've seen their 16 make sure I don't have writing on it? Q. Let's talk about the FDA. Are you 17 testing. 18 Q. Have you seen their reports? 18 referring to the 2019 FDA findings that prompted a 19 MS. PARFITT: Again, if you could be a 20 little more --20 A. Yes. 21 Q. Have you seen the report of any defense 21 Q. Okay. Do you know how many samples the FDA 22 tested in 2019? 22 expert who performed asbestos testing? 23 A. I don't remember, off the top of my head. A. No, I have not. 24 Q. Okay. Do you believe that you're qualified 24 But it was something bot -- so there's a distinction 25 to weigh -- let's strike that question. Start over. 25 between samples and bottles. Page 71 Page 73 Q. Understood. Do you know what X-ray diffraction is? 1 1 2 A. You're asking about samples or bottles? A. No. I don't. 3 Q. I will ask about samples first. 3 Q. Okay. A. Yeah. I don't recall exactly. But it was A. I think we should stop at that line of 5 something about -- it's approximate -- I don't like 5 questioning. I mean, you can ask. You can ask. 6 approximations. It was 52 or -- yeah. I don't want Q. I just like to get a record. Polarized 7 to approximate. 7 light microscopy? A. I mean, I know the name. I can tell you Q. Okay. Understood. If the answer is "no," 9 that can be the answer. 9 what TEM was. But how is that performed? No, I 10 A. Yeah. Yeah. I don't --10 don't. Q. Do you know what percentage of those Q. That was -- the question is do you feel 11 12 samples tested positive? 12 like you're qualified to weigh the strengths and 13 weaknesses of those forms of asbestos testing? 13 A. No. I can't recall. 14 Q. Okay. And do you know how many samples of 14 A. No. 15 J&J baby powder have been tested by the FDA in 15 Q. Okay. 16 16 history? A. I know TEM is better. I mean, I read. 17 MS. PARFITT: Objection. Form. 17 Q. What do you read that says TEM is better? 18 A. No, I don't. I don't. I know that there 18 A. The FDA's, you know, moving towards TEM.

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19 have been many.

Q. You don't know how many of those tested

21 positive in history?

22 A. No.

23 MS. PARFITT: Objection. Asked and

24 answered.

25 Q. Okay. A. Yeah. I mean, the opinion is based on, you

19 Again, I don't want to get into that area of

Q. Well, I think it's important, if you're

22 going to offer an opinion about whether talc takes 23 -- contains asbestos, that we understand what that

20 testing. Yeah.

24 opinion is based on.

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- 1 know, these citations, the EPA report and their, you
- 2 know -- they would be the experts to answer whether,
- 3 you know, the methodology was appropriate. I mean,
- 4 I -- on my reading, it appears to be appropriate.
- Q. When you say "they," are you referring to
- 6 Drs. Longo and Rigler?
- 7 A. Yes.
- 8 MS. PARFITT: He mentioned IARC. He
- 9 mentioned EPA.
- Q. Let me ask it as an open-ended question.
- 12 referring to?
- 13 A. Yeah. When -- obviously, the evidence I
- 14 cite is from the FDA. I mean, so you can go to the
- 15 FDA. You can go to Longo and Rigler. You can go
- 16 to, you know, the EPA and look at their methodology
- 17 and provide -- yeah.
- 18 Q. Let's turn to page 14 of your report.
- 19 A. Sure.
- 20 Q. The final paragraph before Section 8, so
- 21 final paragraph of Section 7, beginning with
- 22 "Vimercati, et al."
- 23 A. Yeah.

4

- 24 Q. You say that Vimercati is a case series
- 25 with four cases: Two with talc exposure, and one

- Page 76 Q. Okay. At your last deposition, you said
- 2 that you would not be offering an opinion on the
- 3 quantity of asbestos exposure necessary to cause
- 4 ovarian cancer. Is that still the case?
- 5 A. That is correct.
- 6 Q. Okay. You mention here "retrograde
- 7 migration of talc." Are you going to be offering an
- 8 opinion that talc can reach the ovaries through
- 9 inhalation?
- 10 A. I mean, I -- some have suggested that.
- 11 When you said "they" in that question, what were you 11 Like, for example, Schildkraut suggests that in her
  - 12 paper, the AACES study. I am, you know -- that's
  - 13 one biologic plausibility opinion that I, you know,
  - 14 included in my 2018 report -- 2018? Yeah.
  - 15 MS. PARFITT: 2018.
    - A. That's one plausible mechanism.
  - 17 Q. Do you have an opinion related to fibrous
  - 18 talc?

16

- 19 A. I mean, I have an opinion related to
- 20 whatever's in the bot -- you know, I was examining
- 21 the association. I was not disaggregating talc,
- 22 talc containing asbestos, fibrous talc. You know,
- 23 what's in that bottle, whatever's -- the studies
- 24 reported, I'm not going to be able to disaggregate
- 25 those components of talc.

- 1 with an identified amphibole fiber of tremolite. Is
- 2 it your standard practice to draw causal conclusions
- 3 from a single case report?
- 5 answered.

MS. PARFITT: Objection. Asked and

- A. No. I'm not drawing any causal conclusion
- 7 from that single -- I mean, again, the causality
- 8 assessment is based on the whole body of evidence. 9 You know, I did a supplement. I found studies. So
- 10 I noted it. So, you know, that one study or case
- 11 series is not going to drive the causal assessment.
- 12 Q. So the answer to the question is no; but,
- 13 also, you didn't do that here.
- 14 MS. PARFITT: Objection. Misstates his
- 15 testimony.
- A. What do you mean by -- ask the question. 16
- 17 Ask the question. Of course, I have to cite. If
- 18 the studies are there, you have to cite the study.
- 19 But the causality assessment is not based on this.
- 20 It is not even predicated on the presence of
- 21 asbestos, you know.
- 22 Q. Understood. At your last deposition, you
- 23 said you were not familiar with the term "cleavage
- 24 fragments." Is that still the case?
- 25 A. Yes.

- Page 77 Q. Who drafted your 2023 supplemental expert
- 2 report?

- 3 A. Me, me, and only me.
- 4 Q. You wrote every word in it?
- 5 A. Every single word in it.
- Q. Okay. Did you have any discussions with
- 7 lawyers before you drafted it?
- 8 MS. PARFITT: Objection to any
- 9 discussions with counsel as to the content.
- 10 Q. Okay. Can you answer that as a yes-or-no
- 11 question without telling me the content of those
- 12 discussions, if they exist?
- 13 MS. PARFITT: Just so I understand,
- 14 Mr. Martin -- I'm not being difficult -- but have we
- 15 talked to him since his 2018 report when we asked --
- 16 advised him that the Court required an updated
- 17 report? Help me out here. Of course we've talked
- 18 to him.
- 19 Q. Okay.
- 20 A. Yeah, I did have a discussion. Yeah.
- 21
- 22 MS. PARFITT: We talked to him about
- 23 coming to this deposition.
- 24 MR. MARTIN: I'm sorry. I meant in
- 25 advance of drafting the 2023 report.

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- A. Yeah. They had to -- because if I hadn't 1
- 2 known it, I wouldn't have drafted it. There would
- 3 have to be a discussion.
- Q. Do you remember approximately how many
- 5 discussions you had?
- A. It was -- that should have been noted in my
- 7 thing because --
- Q. Fair point. If you had a discussion, it
- 9 would be noted on the invoice?
- 10 A. I noted discussion separately and my review
- 11 separately, I think.
- 12 Q. Let me just check and make sure that's
- 13 right.
- 14 A. I hope I did.
- 15 Q. Sounds right but -- telephonic
- 16 consultation?
- 17 A. Yes. So that's the discussion.
- Q. Understood. Did you personally identify
- 19 all of the documents included in your -- all of the
- 20 documents on the reference list of your 2023 report?
- A. The majority. They did provide some
- 22 additional documents, for example, you know, the
- 23 depositions and, you know, Longo's testing so -- and
- 24 the EPA testing. I mean, I had heard about the EPA
- 25 test, and I had it. But I didn't have the full text
  - Page 79

- 1 of it.
- Q. When you received materials from counsel,
- 3 did you ask for those? Or were they provided to you
- 4 without asking?
- A. Some of them, like, I asked them to source
- 6 the references because, you know, I didn't have it
- 7 in my library. So I may have asked one or two
- 8 references for them to source it. Like, I had
- 9 identified it, but in some cases they did provide 10 it.
- Q. Let's look back at your report, page 3. In
- 12 that box there, that contains the search terms that
- 13 you used to identify new articles for your
- 14 deposition?
- 15 A. Yes.
- Q. Okay. And all the articles that were
- 17 responsive to those search terms are included in
- 18 Appendix A to your report; is that right?
- A. Yeah. And the ones that I excluded are --
- 20 there's two lists; right? There's an included and
- 21 relevant list. And there is a potentially, you
- 22 know, excluded is -- the, you know -- the -- some of
- 23 them may have been cited for context. But the ones
- 24 in the references are the main articles that are
- 25 relevant to this report.

- Page 80 Q. Understood. So can we turn to Appendix A?
  - 2 A. Which is?
  - 3 MS. PARFITT: We're referencing the '23
  - 4 report?
  - 5 Q. Right. Appendix A of the 2023 report,
  - 6 which follows the reference list.
  - 7 A. Okay. Yes.
  - 8 Q. Were any studies -- let me back up.
  - 9 There are no rows for which I see multiple
  - 10 Xs under -- let me back up further.
  - The chart includes two columns under
  - 12 "include" and several columns under "exclude." The
  - 13 "exclude" columns would be reasons for which you
  - 14 excluded literature that you identified in your
  - 15 search; right?
  - 16 A. Sure.
  - Q. Okay. And if you listed an article and 17
  - 18 there was an X under an "exclude" category, that was
  - 19 the reason you excluded it?
  - 20 A. Yeah. So just to be clear -- and I think I
  - 21 explained that -- article could be -- have been
  - 22 excluded for multiple reasons. But that Appendix A
  - 23 just denotes one reason.
  - 24 For example, article could have been a
  - 25 duplicate and not have original data as well. But,

- 1 you know, that is as transparent as I could be in
- 2 terms of that.
- Q. You anticipated my next question. So thank
- 4 you. What was your basis for excluding an article
- 5 as nonrelevant?
- A. Well, so I state that in the report. So we
- 7 should look at that. So, I mean, in the section on
- 8 "eligibility criteria," I included epidemiologic
- 9 studies --
- 10 MS. PARFITT: That's page 3.
- 11 O. Yes.
- 12 A. -- which provided data, so they had to
- 13 provide data on association. I included study
- 14 designs. I included, you know, the cohort studies,
- 15 case control studies, umbrella reviews, systematic
- 16 reviews, meta-analysis, pooled analysis.
- 17 I examined the references to find
- 18 additional articles which provided data. I also
- 19 included studies that reported on biological
- 20 mechanisms and causal pathways that either supported
- 21 or refuted the role of talc. And this could include
- 22 different study design.
- 23 When I say, after consideration, I excluded
- 24 narrative reviews or opinion articles that did not
- 25 provide original articles -- original data that are

Page 82 Page 84 1 not deemed relevant, some of them were cited for 1 and ovarian cancer." 2 context, so -- but in terms of the -- you know, my A. Sure. Sure. 3 3 opinion, I am focusing on, you know, systematic Q. You have this marked as not relevant 4 review that have studies that provide data. 4 because it is not a systematic review or Q. How do you define "cited for context"? 5 meta-analysis; is that correct? 6 What exactly do you mean by that? A. That is correct. And does not provide 7 A. Well, they are cited. You know, they are 7 original data. Yeah. 8 cited in the report. Yeah. Q. Okay. Let me ask you about original data. Q. But you seem to be drawing a distinction 9 So -- okay. Yes. So it would be relevant if it 10 between "cited for context" and "cited 10 provided original data, on the one hand, or if it 11 substantively"? 11 was a systematic review or meta-analysis on the 12 A. Yeah. 12 other hand. 13 Q. Can you explain what you mean by the A. Yes. Exactly. So, for example, I mean, in 14 distinction? 14 terms of context, you know, if you look at 62 -- I'm 15 A. Sure. For example -- and I have to, you 15 trying to answer -- your question is -- where is 16 know -- I don't want to make sort of assumptions 16 that Rosner -- 77, Row 77. It's also excluded. It 17 about anything. But, for example, let's see -- I 17 does not have original data. But that is, like, a 18 don't -- I can't come up with -- but, you know, it 18 citation for context. I'm trying to explain why, 19 will be, like, response to an article which 19 you know, because, you know, it was excluded. 20 explains, you know, the underlying -- yeah. So, for Q. So going back to 29, Goodman 2020, it's 21 example, if you look at -- let's see if I can 21 entitled "A systematic review." Can you explain to 22 explain this better. For example -- I can't find 22 me the difference between a systematic review and a 23 that. 23 -- I'm sorry. It's entitled "A critical review." 24 Q. We can --24 Can you explain to me the difference between a 25 MS. PARFITT: Just give him a moment. 25 critical review and systematic review? Page 83 1 He doesn't mind. A. Sure. You know, a systematic review would A. Yeah. I mean, there are -- I'm trying to 2 provide search dates, would provide what are the 3 look through the list of excluded articles. 3 studies they included -- you know, similar to what I Q. I'll withdraw the question. 4 have here -- would provide criteria for inclusion, 5 A. No. No. 5 exclusion and, in many cases, assessment of bias Q. I don't want to spend time on this. I 6 and, if the data are appropriate, do a pooled 7 don't want to spend time on this. I'll withdraw the 7 analysis or -- meta-analysis. Sorry. Q. Let's look at Row 27. This is one that you 8 question. MR. MARTIN: Can we take a break? Off 9 did include as relevant; right? This is Gabriel, et 10 the record. 10 al., "Douching, talc use, and risk for ovarian 11 (A break was taken) 11 cancer and conditions related to genital tract 12 MR. MARTIN: Back on the record. 12 inflammation," 2019. A. Which is --Q. We were looking at Appendix A to your 2023 13 MS. PARFITT: 27, Gabriel. 14 report when we broke. And can we look at Row 29 of 14 15 this? 15 MR. MARTIN: Let's introduce this as an 16 exhibit. 16 MS. PARFITT: Row 29 of Appendix A? 17 MR. MARTIN: Yes. Which should be 17 Q. Sorry. So let's just look at your report, 18 Goodman, et al. 18 again, page 12. 19 THE WITNESS: Yeah. 19 A. Okay. 20 MS. PARFITT: For the record, if you 20 Q. So this is the same document, just going 21 don't mind, since there's two Goodmans. Goodman 21 back to the body of it. You described this as a 22 '23? 22 case control study in the body of your report, so

23 not a systematic review or meta-analysis; right?

Q. Okay. But it's included because it

A. That's what I state here.

24

25

23

24

25

MR. MARTIN: No. Goodman 2020.

MS. PARFITT: 2020. Thank you.

Q. It's entitled "A critical review of talc

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1		:-1	1-4-9
1	contains	originai	uata?

- 2 A. Yeah.
- 3 Q. Just wanted to --
- 4 A. Sure.
- 5 Q. -- put a finer point.
- 6 A. I have to look at -- I want to make sure I
- 7 have it in front of me if you're going to ask
- 8 specific questions.
- 9 Q. Understood. We will probably return to it
- 10 later today, but that was the only question I had at
- 11 this point. Let's go back to Appendix A, Row 92.
- 12 Sorry. There's a lot of flipping through paper
- 13 today.
- 14 A. That's okay, as long as I have it in front
- 15 of me.
- 16 (2021 article by Nicolas Wentzensen, et
- 17 al., Exhibit 12, marked)
- 18 Q. This is Wentzensen, O'Brien, "Talc, body
- 19 powder, and ovarian cancer: A summary of the
- 20 epidemiological evidence" from 2021 --
- 21 A. Yes.
- 22 Q. -- published in Gynecologic Oncology.
- A. That is correct.
- Q. Do you think Gynecologic Oncology is a
- 25 reputable journal?

A. Yes.

- Page 86 1 depending on bias --
  - 2 Q. Let's talk about financial bias
  - 3 specifically. Are you aware of any financial bias
  - 4 they have?
  - 5 MS. PARFITT: Objection. Form.
  - 6 A. No.
  - 7 Q. Okay.
    - MR. MARTIN: Let's mark this as an
  - 9 exhibit. This is the Wentzensen, O'Brien article I
  - 10 just mentioned. I have a wrongly paginated version
  - 11 of this, unfortunately.
  - 12 THE WITNESS: I read it. So you can
  - 13 point --
  - 14 MR. MARTIN: I understand. I need to
  - 15 find my place in it because I have it paginated
  - 16 differently in my outline than it is here.
  - 17 MS. PARFITT: Sure.
  - 18 Q. If you can look at page 8 of the document,
  - 19 halfway through the second paragraph of the
  - 20 conclusion.
  - A. Give me a second.
  - MS. PARFITT: Page 8.
  - 23 Q. Specifically the sentence that starts
  - 24 "Taken together, the epidemiological data from case
  - 25 control studies and cohort studies" ---

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- 2 Q. Have you cited things from it?
- 3 A Yes

1

- 4 Q. I think you cited some things from it in
- 5 your expert report.
- 6 A. Yes.
- 7 Q. Do you know by -- the reputation of either
- 8 Dr. Wentzensen or Dr. O'Brien?
- 9 A. No. But I've read a lot of the articles.
- 10 Q. Do you have any reason to believe that
- 11 they'd be biased one way or another?
- MS. PARFITT: Objection. Form.
- 13 A. I mean, biased in the terms of, you know,
- 14 what kind of bias? You know, bias works in
- 15 different forms. Financially? No. They work at,
- 16 as far as where, you know, NCI.
- But there are other sources of bias, like
- 18 confirmation bias. You know, researchers publish
- 19 findings. And then there are subsequent study --
- 20 they pattern these findings.
- So, you know, I'm not saying that's what
- 22 they have. But there are different kinds of biases
- 23 operational in the literature. And I'm not saying
- 24 something totally out of the ordinary. That's well
- 25 established in the scientific literature. Yes. So

- 1 A. I'm sorry. I'm not there.
- 2 Q. Let me know when you get there.
- 3 A. Page 8 where? Second paragraph?
- 4 Q. Second paragraph of the "conclusion"
- 5 section.
- 6 A. Second paragraph. "Taken together." Okay.
- 7 Got it.
- 8 Q. "Taken together, the epidemiological data
- 9 from case control studies and cohort studies suggest
- 10 that there may be a small positive association
- 11 between genital powder use and ovarian cancer, which
- 12 may be limited to women with patent reproductive
- 13 tracts."

- Do you agree with Wentzensen that there's a
- 15 small association between genital powder use and
- 16 ovarian cancer?
  - MS. PARFITT: Objection. Form.
- 18 A. I mean, I'm not going to qualify it. But,
- 19 you know, they provided and other studies have
- 20 provided evidence that, based on the biological
- 21 mechanisms, there is a positive association between
- 22 genital powder use and ovarian cancer in women with
- 23 patent tracts.
- Q. You mentioned in that answer "biological
- 25 mechanism." Is biological mechanism relevant to

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1 consideration of an association, or is it relevant

- 2 to consideration of causation?
- A. I mean, yeah, causation.
- 4 Q. Okay. Do you agree with the statement that
- 5 it may be limited to women with patent reproductive 6 tracts?
- 7 A. I mean, that is one possible biological
- 8 mechanism. But, you know, if -- and, again, we went
- 9 through this before. But if the other -- there are
- 10 other biological mechanisms such as inhalation,
- 11 then, you know, it may not be limited.
- 12 Q. I guess I'm not asking at this point for a
- 13 discussion of biological mechanism. Do you believe
- 14 that the associations shown in the literature are
- 15 limited to women with patent reproductive tracts?
- 16 MS. PARFITT: Objection. Form.
- 17 A. Not necessarily. I mean, her study broke
- 18 it down, and some of the more recent studies have.
- 19 And that is probably the most likely biological
- 20 mechanism. But other studies have shown in, you
- 21 know -- the earlier studies did not adjust for
- 22 patent tracts. And they still showed -- so if we
- 23 would rely on those studies, then yes.
- Q. Presumably, those studies would include
- 25 women both who have had tubal ligation or

- Page 91
- 1 hysterectomy and those who have not.
- 2 A. Exactly.
- 3 Q. And you just used a pronoun in the last
- 4 answer. You said "she." I assume you mean
- 5 Dr. O'Brien, one of the co-authors in this paper.
- 6 A. I think she's a "she."
- 7 Q. Her name is Katie. I'm going to make that 8 guess.
- 9 A. I also made a guess. I have not met her.
- 10 Q. In the same paragraph, the sentence that
- 11 follows, "Data from a large case control study
- 12 suggested that associations between talc use and
- 13 ovarian cancer were largely confined to
- 14 premenopausal women and postmenopausal women who
- 15 used hormone therapy." And the citation is 39,
- 16 which is Cramer 2016.
- 17 I believe you may have said this in your
- 18 report. But do you agree with Cramer and Wentzensen
- 19 that the association is limited to premenopausal
- 20 women and postmenopausal women with hormone therapy?
- 21 MS. PARFITT: Objection. Form.
- A. You have to point me where I wrote that.
- 23 But, I mean, I see that study and I -- you know,
- 24 this was -- this study was cited in my previous
- 25 report. But I want to make sure that -- what is the

- 1 statement that I'm being asked to comment on.
- 2 Q. Let's just move on. I don't need to dig
- 3 through your report for it.
- 4 Next paragraph of this "conclusion"
- 5 section, the second sentence which -- the third
- 6 sentence, actually, "However, the experimental and
- 7 animal carcinogenicity data for talc are limited and
- 8 inconclusive. There are currently no good animal or
- 9 experimental models of ovarian carcinogenesis that
- 10 could be used to more directly test biological
- 11 effects of talc."
- 12 A. Where are you?
- 13 Q. I apologize. It's two sentences down.
- 14 A. Got it. Yeah.
- 15 O. You see where it is --
- 16 A. Yes.
- 17 Q. Okay. The question I have is whether you
- 18 agree that there are currently no good animal or
- 19 experimental models of ovarian carcinogenesis.
- 20 MS. PARFITT: Objection. Form.
- 21 Misstates his testimony.
- MR. MARTIN: The question is whether he
- 23 agrees.
- A. So I think, you know, assessment of
- 25 causality is, you know -- she -- she's making a

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- 1 statement. Does not make a -- you have to examine
- 2 animal models. You have to examine experimental
- 3 models, but it is really about biologic
- 4 plausibility.
- 5 And she, actually, in a recent paper on
- 6 fibroids provides the best example of an
- 7 experimental model where she talks about migration,
- 8 inflammation and epithelial cells. And we can
- 9 initiate a series of mutagenic events that can lead
- 10 to cancer as well as -- and if -- which is even
- 11 worse with asbestos.
- So in my mind, that's an experimental
- 13 model. I'm not sure what experimental model -- that
- 14 term means. Is it some -- you know, I don't know if
- 15 she is thinking about every step in the carcinogenic
- 16 process. I don't really know what the term means.
- 17 Q. Let's focus on -- do you agree that there
- 18 are no good animal models of ovarian carcinogenesis?
  - MS. PARFITT: Object. Objection.
- 20 Misstates the prior testimony.
- 21 A. Yeah. I'm not aware of good animal models.
- Q. Halfway down the same paragraph -- and I'll
- 23 slow down this time to make sure everyone is
- 24 there --

19

MS. PARFITT: Thank you.

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- Q. -- it's the sentence starting "Other 1 2 components."
- A. Yes. I have it.
- Q. Okay. "Other components of body powder,
- 5 including cornstarch, could also possibly play a
- 6 role in carcinogenesis by inducing inflammation in
- 7 the reproductive tract. But carcinogenicity data
- 8 are lacking." Do you have an opinion about the
- 9 carcinogenicity of non-talc components of body 10 powder?
- 11 A. I have not evaluated that.
- 12 Q. And body powder that is not -- cornstarch
- 13 body powder you have not evaluated.
- A. I've used "genital talc," yeah.
- 15 Q. So there's a different product that is
- 16 cornstarch body powder. You haven't evaluated that?
- A. No. I mean, some of the studies talk about
- 18 it. But I haven't eval -- my opinion is limited to
- 19 genital talcum powder use.
- 20 Q. The next sentence -- the next two
- 21 sentences, "Confounding by indication may explain
- 22 some of the observed associations. This would occur
- 24 conditions that are associated with ovarian cancer
- 25 were also more likely to use body powder in the
  - Page 95

- 1 genital area."
- The first question is whether you agree
- 3 that confounding by association is a possibility to
- 4 be considered.
- 5 MS. PARFITT: Objection.
- Q. Excuse me. That confounding by indication
- 7 is a possibility to be considered.
- A. Yeah. And, you know, A, you have to
- 9 consider it in epidemiologic studies of association,
- 10 any kind of confounding. And you have to consider
- 11 confounding by indication.
- 12 I'm not sure this would be operational
- 13 because we are talking about exposure outcome
- 14 relationship that takes years. We're not talking
- 15 about you use it, you know, today and you have
- 16 cancer tomorrow.
- 17 So, you know, if women had irritation in
- 18 something and they had the first symptoms of -- so
- 19 it's really about -- "confounding by indication" is
- 20 a very specific term. And it means that you are
- 21 using it for indication for that disease.
- 22 And, in fact, there's good studies to
- 23 suggest that, you know, it is more operational when
- 24 you're thinking about drugs and efficacy, you know,
- 25 like, ACE inhibitors and stroke and something that

- 1 provides benefit. It is less operational when
  - 2 you're thinking about harmful effects.
  - So I don't think confounding by indication
  - 4 is a consideration. There could be a consideration
  - 5 about confounding, per se, but not necessarily
  - 6 confounding by indication; or if it is, it's very 7 low.
  - 8 Q. Do you think it's possible that obese women
  - 9 are more likely to use talcum powder than nonobese
  - 10 women?
  - 11 MS. PARFITT: Objection to form.
  - 12 A. You would have to have data showing that,
  - 13 you know, it is -- you know, that -- you know,
  - 14 obesity is a risk factor for -- you know, we know
  - 15 that. But the question then would be is -- are
  - 16 women that are obese -- you'd have to fulfill the
  - 17 criteria for confounding.
  - 18 You have to have obesity association with
  - 19 cancer -- we know it is, several studies -- obesity
  - 20 association with exposure, in this case, and then
  - 21 obesity not mediating the pathway. You'd have to go
  - 22 to specifics. But that is not confounding by
- 23 if women with hormonal or inflammatory exposures or 23 indication. That's not an indication for ovarian
  - 24 cancer. That's confounding, yes, but -- and you
  - 25 have several studies have adjusted for that.
  - But I disagree with her about confounding 2 by -- I think she's using the term very generally
  - 3 but not specifically. She could have been more
  - 4 specific about confounding.
  - Q. Okay. Can you -- and I appreciate the
  - 6 context. But can you just try to give a yes-or-no
  - 7 answer to the question of whether you believe it's
  - 8 possible -- not established but possible -- that

  - 9 obese women are more likely to use talcum powder?
  - 10 MS. PARFITT: Objection. Asked and
  - 11 answered.
  - 12 A. I don't -- I have to look at the data and
  - 13 say.
  - 14 MS. PARFITT: You've answered the
  - 15 question.
  - Q. Can you review the first paragraph on the
  - 17 next page -- just let me know when you've reviewed
  - 18 it -- beginning "Independent of the underlying
  - 19 cause"?
  - 20 A. Yeah. Yes. First paragraph. Okay.
  - 21 Q. Yeah. Second sentence, "The low relative
  - 22 risk translates to a very low absolute risk
  - 23 increase, given the rarity of ovarian cancer" and
  - 24 then later down the page, "Given the widespread use
  - 25 of powders and the rarity of ovarian cancer, the

Q. Okay. Does the fact that talc is

2 associated with various subtypes of cancer affect

MS. PARFITT: Objection. Form.

Q. Sure. One of the viewpoints that Dr. Hill

Q. Okay. And we just talked about the fact

3 your analysis of the specificity criterion of the

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- 1 case for public health relevance is limited." Do
- 2 you agree or disagree with the statement that the
- 3 case for public health relevance is limited?
- 4 A. I disagree because that's, you know -- the
- 5 reason I disagree is, you know, it's not just about
- 6 relative risk. And it's not just about the
- 7 prevalence of exposure. And as you know, we've seen
- 8 studies, many studies, where they talk about give or
- 9 take there are 20,000 incident ovarian cancers in
- 10 the US and -- annually and the PAR.
- 11 So at least at the population level, you
- 12 are getting -- Davis and Wu provide an estimate.
- 13 And I don't recall the specifics, but we can look at
- 14 that. So that means there is a preventible cause of
- 15 risk factors. Why would that -- why wouldn't it be
- 16 relevant for public health?
- 17 MR. MARTIN: Can we go off the record
- 18 for just a moment while I go through my notes?
- 19 (A break was taken)
- MR. MARTIN: Back on the record.
- 21 Q. Can you turn to page 4 of the Wentzensen
- 22 article we were discussing before the break? The
- 23 First sentence of 4.1, "Ovarian cancer is
- 24 characterized by profound heterogeneity that can be
- 25 observed in site of origin, genetic susceptibility,

11 that epithelial ovarian cancer contains several 12 subtypes.

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- 14 Q. Does the fact that it contains several
- 15 subtypes -- let me start that one over.

A. Can you restate? Sorry.

8 talks about is specificity; right?

- Did you consider the fact that it contains
- 17 several subtypes when you were evaluating the
- 18 specificity viewpoint?

4 Bradford Hill analysis?

A. Yeah.

A. Sure.

- 9 A. I don't think that that is, you know, the
- 20 relevance of -- if you -- and we should pull the
- 21 Bradford Hill article. I don't know what the
- 22 reference -- can we pull it out?
- The reason I'm saying that is I don't think
- 24 that is the consideration there. It's more the
- 25 consideration of "Is that etiology the only cause of

Page 99

- 1 somatic mutations, molecular pathways, risk factor
- 2 associations, and morphologic differences." Do you
- 3 agree with that statement?
- 4 A. Yes.
- 5 Q. Do you agree that that statement is true
- 6 for epithelial ovarian cancer specifically?
- 7 A. I mean, that's what I think she's talking
- 8 about; right? She's talking about --
- 9 Q. But we talked earlier about your opinion
- 10 that talc causes all epithelial ovarian cancers.
- 11 A. Yeah. Because that's what I evaluated.
- 12 Q. And did you consider this heterogeneous
- 13 nature of ovarian cancer as part of your opinion?
- 14 A. My -- you know, so my overall opinion was
- 15 based on whatever the studies reported on and --
- 16 which included these various cancers. When notable,
- 17 I did note -- for example, if you go back to my
- 18 previous report, I did note what specific cancers
- 19 they were reporting on. But I did not disaggregate
- 20 that particular -- that talc only is associated with
- 21 X and Y.
- Q. Would you agree with me that the
- 23 overwhelming majority of epithelial ovarian cancers
- 24 are serous?
- 25 A. Yes. By, you know -- just by prevalence.

- 1 that cancer or whatever outcome?" So it's that --
- 2 just because it's etiologic heterogeneity I don't
- 3 think -- and in any way, you know, I did not weigh
- 4 specificity very heavily, because, in fact, I don't
- 5 -- I can look at the exact words -- because ovarian
- 6 cancer has multicausal, you know, risk factors so --
- 7 but it's not because of the fact that it is
- 8 etiologic, you know, heterogeneity. It's just that
- 9 there are different causes.
- 10 Q. Okay. Can you explain to me the difference
- 11 between different causes and etiologic
- 12 heterogeneity?
- 13 A. Yeah. I mean, different causes are, like,
- 14 you know -- like, say if you say -- I don't know --
- 15 "What are the established risk factors?" You know,
- 16 we could go back and look at a list and say, you
- 17 know, "Obesity increases the risk of causes of
- 18 ovarian cancer." Those are causes.
- 19 For a moment let's, you know, think that
- 20 obesity -- but that does not get into etiologic
- 21 heterogeneity. Here, we are talking about different
- 22 types of cancer. That's etiologic heterogeneity.23 Q. Okay. So this Wentzensen and O'Brien
- 24 article, you exclude it because it's not a meta-
- 25 analysis or original data; right?

26 (Pages 98 - 101)

	Page 102		Page 104
1	A. Yeah. I mean, you know, it is important.	1	(2023 article by Katie M. O'Brien, et
2 I	t's, you know, included in my list of I reviewed	2	al., Exhibit 13, marked)
3 i	t. But it did not provide original data. I mean,	3	Q. Can you look at the O'Brien 2023 article
4 r	nost of the opinions are, you know, derived from the	4	that was marked as Exhibit 13?
5 p	previous publication that are included and	5	A. Sure.
6 c	considered, you know. So it's not excluded in that	6	Q. In particular, can you look at the end of
7 s	sense. But it is in my list of reviewed documents.	7	the second body paragraph, the last sentence of that
8	Q. Are you aware of a different article by	8	paragraph, "However, if historic use cannot be
9 (	D'Brien, Wentzensen along with Ogunsina and Sandler	9	accurately recalled, measurement error can bias
10 e	entitled "Douching and genital talc use: Patterns	10	effect estimates, especially if recall reliability
11 c	of use and reliability of self-reported exposure"?	11	differs by outcome status."
12	A. Yes.	12	A. Which page? I'm sorry. I missed it.
13	Q. Okay. I did not see that on your reliance	13	Q. It's the first page, page 376, of the
14 1	ist. Did you review it in drafting your expert	14	journal pagination. But it's the first page of the
15 r	report?	15	article.
16	A. I know I'm aware of it. I don't know when	16	A. Where are we?
17 I	reviewed it. But yeah, I did review it. Yeah.	17	Q. It's the second paragraph of the body.
18	Q. Okay. Is there a reason it wouldn't be on	18	A. Okay.
19 y	your reliance list?	19	Q. It's the final sentence beginning
20	A. You know, it could I'll have to look at	20	"However."
21 i	t and see why not but what was the year of	21	A. Yeah.
22 p	publication?	22	Q. Okay. That's talking about the concept of
23	Q. 2023.	23	recall bias; right?
24	A. Okay. When in '23?	24	A. Uh-huh.
25	MR. TISI: I think it was December 2023,	25	Q. And do you agree that recall bias can pose
	Page 103		Page 105
1 i	f I'm not mistaken.	1	a problem in a retrospective epidemiological study?
2	f I'm not mistaken.  THE WITNESS: It could be earlier.	1 2	a problem in a retrospective epidemiological study?  A. That is correct.
2 3	f I'm not mistaken.  THE WITNESS: It could be earlier.  MR. TISI: But I think it is December.	l	<ul><li>a problem in a retrospective epidemiological study?</li><li>A. That is correct.</li><li>Q. Okay. If you look at the next sentence,</li></ul>
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MR. MARTIN: Four lines. Starts with 1

2 "The reliability." THE WITNESS: Yeah. 3

Q. "The reliability measures for genital talc

5 use were similar for ovarian cancer compared to the

6 full sample. However, while self-reported use in

7 the 12 months before enrollment was more commonly

8 reported on the enrollment questionnaire -- 27

9 percent -- relative to the fourth detailed follow-up

10 questionnaire -- 21 percent -- in the full sample,

11 the trend was reversed among those with intervening

12 ovarian cancer diagnoses, with 28 percent

13 self-reporting genital talc use at enrollment and 33

14 percent self-reporting genital talc use on the

15 follow-up questionnaire." Let's unpack this a

16 little bit.

17 For the full sample, it looks like self-

18 reported talc use was higher at the beginning than

19 it was in a later follow-up questionnaire, 27 to 21.

20 A. Give me a second to read.

21 O. No problem.

22 A. There's so many different things here.

23 Yeah. So self-reported use in the 12 months before

24 enrollment was more commonly reported in the -- 27

25 to -- okay. Yeah. Got it.

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- Q. So does that suggest that some women may 1
- 2 have underreported their exposures in the later 3 questionnaire?
- 4 MS. PARFITT: Objection. Form.
- 5 A. I'm not sure that's what it suggests.
- Q. What else could it suggest?
- 7 A. Well, you know, there's -- is it the same
- 8 sample? For example, if you look at the same --
- 9 paragraph down, I mean, half of the women diagnosed
- 10 with ovarian cancer expired. So are we looking at
- 11 the same sample? Before we can even interpret these
- 12 numbers -- so if you had women with -- if you are
- 13 losing the sample, I can't compare the estimates --
- Q. Well, this is the full sample; right? It's
- 15 not the sample limited to ovarian cancer-diagnosed
- 16 women.
- 17 A. Yeah. But it is following -- it is the
- 18 full sample. Then you have to get to the fourth
- 19 questionnaire; right? You have to get to the fourth
- 20 questionnaire. Between the enrollment and the
- 21 fourth questionnaire -- that's what they're saying
- 22 -- half of the women diagnosed -- so at least
- 23 relevant to the ovarian cancer, I don't know how to
- 24 interpret these numbers as being decreased reporting
- 25 or increased reporting.

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- I mean, it's probably not increased. But,
- 2 you know, it's not the same sample that began and
- 3 the same sample that reported at the end.
- Q. Do you have any reason to believe that the 5 people who dropped --
- MS. PARFITT: No. Please. Go ahead.
- 7 Q. Do you have any reason to believe that the
- 8 people who dropped out between the first and fourth
- 9 questionnaire would be systematically as opposed to
- 10 randomly different than the group as a whole?
  - A. I mean, we'll have to look at, you know,
- 12 who are the dropouts; what are their
- 13 characteristics; how much was the dropout. And
- 14 we'll have to look at that.
- 15 And, you know, particularly if dropout is
- 16 related to something with talc, such as ovarian
- 17 cancer, then these estimates become, you know --
- 18 were people taking it, getting ovarian cancer, and
- 19 then dropping out? I don't know.
- 20 Q. Let's look at the subgroup that does
- 21 involve intervening ovarian cancer diagnoses, which
- 22 is the second half of that sentence. "The trend was
- 23 reversed among those with intervening ovarian cancer
- 24 diagnoses, with 28 percent self-reporting genital
- 25 talc in enrollment and 33 percent self-reporting

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1 genital talc use on the follow-up questionnaire."

- 2 So in that group that had an intervening
- 3 ovarian cancer diagnosis, more people reported talc
- 4 use after the diagnosis than before. Is that your
- 5 understanding?
- A. No. 6
- 7 Q. No, it's not?
- A. I think you can't compare the samples. I
- 9 mean, you know, they are comparing. That's fine.
- 10 But to interpret these numbers, you'd have to know
- 11 attrition, attrition by talc, and their
- 12 characteristics. I can't really -- I can't affirm
- 13 the conclusions that 28 increased with 33 is
- 14 consistent.
- 15 Q. Let's look at what the authors of this
- 16 article said about those numbers, and let me try to
- 17 point you in the right direction.
- 18 A. Can you give me one minute to read this?
- 19 O. Sure.
- 20 MS. PARFITT: Thank you.
- 21 Q. Happy to have you read it briefly on the
- 22 record. If you're going to take a long time, I'd
- 23 like to go off the record.
- 24 A. No. No.
- 25 MS. PARFITT: Finish. Are you done?

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- 1 A. One more. Yeah. Ask the question, if
- 2 there's a question. I'll --
- 3 Q. Let's look at the next sentence. "This was
- 4 the only subgroup for which the proportion of users
- 5 increased between enrollment and follow-up and could
- 6 indicate recall bias, i.e., over-reporting of talc
- 7 use among those with a history of ovarian cancer."
- 8 That's, I think, what we were talking about earlier.
- 9 Do you disagree with that statement there?
- 10 A. Yeah. I mean, I don't think that that's
- 11 what the results, you know, can be interpreted as.
- 12 I mean, for example, if you go back to the methods,
- 13 they say that, because the enrollment questionnaire
- 14 did not collect information between age 14 and one
- 15 year, it was impossible for a participant to report
- 16 never use on the enrollment and ever use on follow-
- 17 up without contradicting themselves.
- 18 Q. But in the full -- well, I'll put that
- 19 aside. Let's look at the next column, the end of
- 20 the first paragraph, "The observed increase."
- 21 MS. PARFITT: Page? I'm sorry.
- MR. MARTIN: Again, page 383, the same
- 23 page.

1

- MS. PARFITT: I appreciate that.
- 25 A. The second column?

1 recall bias here.

- Q. Do you have a reason that the amount of
- 3 recall bias would be different in the surviving
- 4 group than the non-surviving group?
- 5 A. It could be. Yeah. I mean, without
- 6 looking at the characteristics, you -- and, you
- 7 know, I mean, it's not a small number as
- 8 approximately half the women diagnosed with ovarian
- 9 cancer expire.
- 10 Q. I just want to follow up. You said "it
- 11 could be different." Do you have any bases here
- 12 today for why it would be different?
- MS. PARFITT: Objection. Asked and
- 14 answered.
- 15 A. Yeah. I mean, you know, I don't -- I don't
- 16 have that data because they don't provide the data
- 17 on the women who expired and what are their
- 18 characteristics.
- 19 Q. Even if you disagree with some of the
- 20 conclusions drawn by the authors of this article, do
- 21 you think the article is relevant to your
- 22 supplemental report?
- 23 A. Yeah. So the question about relevance and
- 24 the reason now I recall is -- I obviously included
- 25 it in the list. And this is a discussion -- it does

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- Q. Second column beginning "The observed."
- 2 A. Beginning the -- which -- second paragraph?
- 3 Q. The first paragraph, the paragraph that
- 4 carries over from the previous.
- 5 A. Yeah.
- 6 O. "The observed increase."
- 7 A. Yeah.
- 8 Q. "The observed increase in self-reported
- 9 genital talc use at follow-up relative to enrollment
- 10 among ovarian cancer survivors may indicate recall
- 11 bias is present and potentially driving some of the
- 12 previously observed differences in effect estimates
- 13 between studies collecting genital powder exposure
- 14 status retrospectively versus prospectively."
- 15 A. It's interesting. That line is very
- 16 interesting, I mean, because, A, you did not collect
- 17 as they -- I'll restate it. They did not collect
- 18 between 14 and one year before enrollment. So
- 19 that's one.
- 20 And they're talking about ovarian cancer
- 21 survivors. Well, what happens to women who get
- 22 ovarian cancer? How many survive? So we have a
- 23 highly lethal cancer. So the sample -- you know,24 you'd have to look at all people -- survivor,
- 25 non-survivors -- to really make a judgment about

- 1 not provide direct data on talc and ovarian cancer.
- 2 But it discusses recall bias in the Sister Study.
- 3 But there's no data on talc and ovarian
- 4 cancer, per se, in this article, that it decreases
- 5 ovarian cancer or increases. Either way, it does
- 6 not refute. That's not the focus of this article.
- 7 I mean, is there somewhere that I didn't miss?
- 8 O. No.
- 9 A. Yeah. So it does not provide any -- as I
- 10 outlined in the methods, I was looking at original
- 11 data on talc and ovarian cancer.
- 12 Q. Is this article in your Appendix A under
- 13 the excluded articles?
- 14 A. No. I don't think so.
- 15 Q. Okay.
- 16 A. Yeah.
- 17 Q. There a reason why it wasn't even in the
- 18 excluded list in Appendix A?
- 19 A. Yeah. I don't recall -- I mean, there were
- 20 so many references that, you know, I examined. So
- 21 -- but, again, it does not provide the data on talc
- 22 and ovarian cancer. But it's not that it's not --
- 23 you know, there's -- we discussed it and, you know,
- 24 addressed as issues around recall bias.
- 25 Q. Generally, do you believe that everything

29 (Pages 110 - 113)

- 1 responsive to your Scopus and PubMed search queries
- 2 should be in Exhibit A?
- 3 A. Yeah. Yeah.
- 4 Q. Okay. You can put that aside. Is it
- 5 standard practice in your experience for authors of
- 6 scientific literature to disclose conflicts of
- 7 interest if they're serving as a litigation expert?
- 8 A. Any kind of -- you know, either litigation
- 9 expert or consulting for the company or doing
- 10 something else. I mean, it's standard practice.
- 11 Journals require it. It's not an optional thing.
- 12 Q. Have you published on talc and ovarian
- 13 cancer --
- 14 A. No.
- 15 Q. -- since becoming an expert? If you were
- 16 to do so, though, you would note your --
- 17 A. For sure.
- 18 Q. -- conflict of interest. Okay. And as a
- 19 reader of scientific literature, is it something you
- 20 consider important when you're evaluating a
- 21 scientific study?
- 22 A. I mean, it is a factor among other factors,
- 23 bias. I mean, the predominant factor is
- 24 methodology. I mean, that is the driving factor.
- 25 But, yes, bias --funding bias, you know, whether

- Page 116
- 1 Q. When you were performing your qualitative
- 2 evaluation of the studies in your expert report, did
- 3 you consider whether an article author was a paid
- 4 litigation expert?
  - MS. PARFITT: Objection. Form.
- 6 A. I mean --

5

- 7 MS. PARFITT: Please answer.
- A. Yeah. I mean, I considered it. But,
- 9 again, I think I answered the question -- is that
- 10 the primary consideration was, A, what is the
- 11 methodology they're talking about? What are the
- 12 issues at stake? And, you know, obviously whether
- 13 they are experts is a consideration.
- 14 Q. All else being equal, would you have fewer
- 15 bias concerns with a paper published by a neutral
- 16 author than by a defense expert?
- 17 MS. PARFITT: Objection.
- A. I mean, I think that, to me -- I hate to
- 19 say it -- but in this realm, I mean, there have been
- 20 so many papers published by defense experts as well
- 21 as, you know, some papers by experts in plaintiffs
- 22 that if one were to start excluding all those, then,
- 23 you know, the body of literature would be, like --
- 24 why -- you have to -- I mean, if it comes up peer-
- 25 reviewed literature, I have to evaluate.

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1

- 1 it's manufacturer, whether it's expert witnesses or
- 2 testimony, consultants.
- It is a factor. And the way it is a factor
- 4 is interpretation, you know. One has to rely that
- 5 the findings in the peer-reviewed literature, at
- 6 least to the extent that they've been undergoing
- 7 peer review, are, you know, rigorous. And, you
- 8 know, obviously one has to examine the methods. But 8
- 9 disclosure is important.
- 10 Q. Is there a way -- did you perform -- did
- 11 you quantitatively weigh the importance of the
- 12 studies included in your 2023 expert report?
- 13 A. No.
- 14 Q. Okay. Is there a way we could tell from
- 15 reviewing your report whether one study was more
- 16 important than another in the formation of your
- 17 opinion?
- 18 A. I mean, you'd have to look at the
- 19 description about strength and limitations. But,
- 20 again, that's not a numerical value.
- 21 Q. Is the fact that an author is --
- MR. MARTIN: Can we take a break here?
- 23 Go off the record.
- 24 (A break was taken)
- MR. MARTIN: Back on the record.

- Page 117 And if the methodology is sound, then, you
- 2 know, you have to acknowledge that yes, they are.
- 3 And -- but you have to go by the methodology really.
- Q. So it is something you acknowledge?
- 5 MS. PARFITT: Objection. Form.
- 6 A. Yeah. I mean, I may not have stated it
- 7 explicitly. But that is important to acknowledge.
- 8 MR. MARTIN: Let's break for lunch. Off 9 the record.
- 10 (A break was taken)
- 11 MR. MARTIN: Back on the record. So
- 12 let's mark as Exhibit 14 Gabriel 2019, "Douching,
- 13 talc use, and risk for ovarian cancer."
- 14 (2019 article by Iwona M. Gabriel, et
- 15 al., Exhibit 14, marked)
- 16 Q. You've seen this document before; right?
- 17 A. Yes.
- 18 Q. You cite it in your 2023 report; right?
- 19 A. That is correct.
- Q. And this is a case control study from 2019;
- 21 right?
- A. That's correct.
- Q. And it's the same data that were previously
- 24 reported in Cramer 2016?
- 25 A. I'm not sure entirely. I mean, I didn't

30 (Pages 114 - 117)

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- 1 duplicate, you know -- this was a new study,
- 2 provided data on association between talc and
- 3 ovarian cancer. Yeah. But it did include, you
- 4 know, the eastern Massachusetts and New Hampshire
- 5 cohort, you know -- cohort.
- Q. If you look at 1835, which is the first
- 7 page, under "materials and methods," you'll see
- 8 "Details regarding enrollment are described
- 9 elsewhere." Then it's Reference 10. Then
- 10 Reference 10 is to the Cramer 2016 article. Do you
- 11 see that?
- 12 A. Yes.
- 13 Q. Okay. In fact, Dr. Cramer is also a
- 14 co-author on this article; right?
- 15 A. Yes.
- 16 Q. Okay. We talked a little bit before lunch
- 17 about litigation conflicts. So let's check the
- 18 second-to-last page, "Disclosure of potential
- 19 conflicts of interest." Do you see that? 1843.
- 20 A. Uh-huh.
- 21 Q. "A.F. Vitonis has provided statistical
- 22 programming to support expert testimony for Beasley
- 23 Allen law firm. D.W. Cramer has provided expert
- 24 testimony for Beasley Allen law firm." Does this
- 25 say what the subject of Dr. Cramer's expert
- Page 119
- MC DADEITT. Objection to "not
- 2 reader would want to know."
- 3 Q. Does it say who Beasley Allen represented?
- 4 A. No.

2

1 testimony was?

A. No.

- 5 Q. Okay. You're aware that Dr. Cramer is a
- 6 plaintiffs' expert in talc litigation; right?
- 7 A. I'm not sure he is, but he was at some 8 point.
- 9 Q. I'm sorry. Yes. You're aware that he was.
- 10 A. Yeah. At some point in time.
- 11 Q. Would the fact that the litigation
- 12 referenced in the conflicts of interest disclosure
- 13 involved talc be something that would be relevant to
- 14 you as a reader?
- 15 MS. PARFITT: Objection. Form.
- 16 A. Can you restate the question?
- 17 Q. Sure. Do you understand this testimony
- 18 that Dr. Cramer provided for Beasley Allen to be
- 19 related to talc?
- 20 A. Yes.
- Q. Okay. Do you think that a reader who is
- 22 not involved in the litigation would understand
- 23 that?
- 24 MS. PARFITT: Objection as to what
- 25 another reader would understand or not.

- MR. MARTIN: Understood.
- 2 A. I mean, they would go through -- if they
- 3 went through Beasley Allen, yes, they could. But I
- 4 don't -- I can't put myself in their situation.
- 5 Q. Okay. You'd agree it doesn't explicitly
- 6 say that.

1

11

22

- 7 A. Exactly.
- 8 Q. Is the fact that it involves talc something
- 9 that would be relevant for you to know?
- 10 MS. PARFITT: Objection. Form.
  - A. Right. For me, it doesn't because -- so
- 12 when I look at articles and the disclosure, when I
- 13 look at a disclosure section, I'm assuming that
- 14 disclosure is relevant. That's why they're making
- 15 the disclosure. I mean, it's either funding or --
- 16 you know, it's NIH, NCI, we do disclose. FDA, I
- 17 disclose. And/or if it's expert testimony, then
- 18 it's relevant to the subject matter at hand. But,
- 19 obviously, it's not explicit here.
- 20 Q. Would you as a reader want to know whether
- 21 he consulted for defendants or plaintiffs?
  - MS. PARFITT: Objection. Form.
- A. I can't tell the reader -- I mean, I know
- 24 and, you know -- potential reader would want to
- 25 know, yes, I mean.

- 1 MS. PARFITT: Objection to "potential
- 3 Q. Did you consider Dr. Cramer and
- 4 Dr. Vitonis's conflict of interest when you were
- 5 evaluating this paper for your expert report?
- 6 A. As I stated earlier, I think my answer to
- 7 that question will be sort of consistent, and, you
- 8 know, I -- I'm aware of it. But, you know, it's the
- 9 methodological issues.
- 10 This is a supplemental report of -- what --
- 11 17, 20 pages. I'm aware of those conflicts, and I
- 12 consider it. But I don't think that was the major
- 13 consideration. It's the methodologic issues. The
- 14 fact they provided new data and the fact that they
- 14 fact they provided new data and the fact that
- 15 reported an increased risk, those are the
- 16 considerations.
- 17 Q. You don't note that fact in your report?
- 18 A. No, I don't.
- 19 Q. You'd agree with me?
- 20 A. But I did consider it.
- Q. Can we turn to the next page, 1844,
- 22 "Acknowledgments," second column, "The costs of
- 23 publication of this article were defrayed in part by
- 24 the payment of page charges. The article must,
- 25 therefore, be hereby marked 'advertisement' in

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- 1 accordance with 18 USC, Section 1734 solely to
- 2 indicate this fact." Did you notice this disclaimer
- 3 when you initially read the Gabriel article?
- 4 A. Yeah. I mean, I focused on the
- 5 acknowledgments, and I focused on the disclosure. I
- 6 did not notice that in the disclaimer as an
- 7 advertisement.
- 8 Q. Have you seen a disclaimer like that in the
- 9 scientific literature before?
- 10 A. I mean, I've not gone and looked for it,
- 11 but.
- 12 Q. So the answer to the question is "no"?
- 13 A. No.
- 14 Q. Okay. Let's --
- MS. PARFITT: I object to that.
- 16 Misstates what he said. He said he's not looked for
- 17 it.
- 18 A. To clarify that -- since we are on the
- 19 topic -- to the disclaimer part, yes, the cost of
- 20 publication was defrayed. I mean, we also put it.
- 21 But the second part, you know, I have not seen.
- 22 Q. Understood. So it's the second sentence --
- 23 A. About advertisement.
- 24 Q. Okay.
- 25 A. But the costs, yes, we -- in fact, my

- 1 Q. Can I refocus the question?
  - 2 A. Sure.
  - 3 Q. The fact that slightly more cases than
  - 4 controls had reported exposure to genital talc would
  - 5 be consistent with an increase in risk; correct?
  - 6 A. Yes.
  - 7 Q. Okay. Let's look at the next row, women
  - 8 who have had a tubal ligation. Okay?
  - A. Yes.
  - 10 Q. 36.5 percent of cases and 26 percent of
  - 11 controls reported using genital talc; correct?
  - 12 A. Yes.
  - 13 Q. Okay. You'd agree with me that's a larger
  - 14 difference than the difference for women who
  - 15 reported tubal ligation?
  - 16 A. Yeah. But the overall numbers are so
  - 17 small. I mean, if you look at the sample size, we
  - 18 are talking about 541 cases versus 440 controls and
  - 19 then 101 versus, you know, 310. So it's -- sorry --
  - 20 Q. Okay.
  - 21 MS. PARFITT: Let him finish.
  - MR. MARTIN: I'll let you finish.
  - A. 101 versus 310, those are not comparable.
  - 24 But the magnitude of the difference is higher.
  - 25 Q. Okay. How do you explain the fact the
- Page 123

- 1 recent article has that.
- Q. Can you look at Table 1 in the body of the
- 3 report, which is on page 1837? Towards the bottom,
- 4 you can look at "tubal ligation." Just tell me when
- 5 you've gotten there.
- 6 A. Yes.
- 7 Q. Okay. So you look at the cases -- which
- 8 would be the women with ovarian cancer; correct?
- 9 A. Uh-huh.
- 10 Q. Okay.
- 11 A. Yes. Yes.
- 12 Q. And you see that 30.7 percent of them --
- 13 looking at the women -- I'm sorry. Looking at the
- 14 women who have not undergone tubal ligation, you see
- 15 that 30.7 percent of the cases had used genital
- 16 talc.
- 17 A. Yes.
- 18 Q. And 26.2 percent of the controls?
- 19 A. Yes
- Q. And that would be consistent with what
- 21 you'd expect if talc were associated with a slight
- 22 increase in risk; correct?
- 23 MS. PARFITT: Objection. Form.
- 24 A. Let me just get back to the numbers. Give
- 25 me a second.

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- 1 magnitude of the difference is higher among women 2 who have had a tubal ligation than among women who
- 3 have intact genital tracts?
- 4 A. I mean, their primary analysis focused on,
- 5 you know, reporting risks based on adjustment
- 6 factors and the reported increased risk. It is
- 7 entirely plausible that it is even increased in
- 8 those who have tubal ligation. So that, you know --
- 9 it's not that those findings are incompatible with
- 10 biological plausibility.
- 11 Q. I guess I'm asking why the difference in
- 12 risk would be larger among women with tubal ligation
- 13 than among women without.
- 14 A. First of all, none of the tests that -- if
- 15 you look at the -- if you're looking at the -- the
- 16 difference is not -- is not -- I would say 30.7,
- 17 26.2 -- and, you know, tests for interactions there
- 18 are not significant. So I don't see that as being
- 19 any materially different.
- Q. So do you think it's just maybe statistical
- 21 noise?
- A. Could be statistical noise.
- 23 Q. Okay.
- 24 A. I mean, not noise. I would say, I mean, it
- 25 is a finding. So you have to go by what they

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- 1 reported. But it is entirely plausible that women
- 2 who had tubal ligation also had an increase. The
- 3 magnitude of -- I think the magnitude of risk is
- 4 sort of not a relevant -- very relevant
- 5 consideration right here.
- Q. You mentioned that the -- strike that.
- 7 You'd agree that the authors of Gabriel
- 8 2019 did not calculate separate odds ratios for
- 9 women with intact tubes and women without?
- 10 A. They adjusted for it.
- 11 Q. Correct. But they did not calculate
- 12 separate ratios.
- 13 A. No.
- 14 Q. Okay. So we talked about this involving
- $15\,$  some of the same cases and controls as Cramer. So I
- 16 do want to look at the Cramer study, Cramer 2016.
- MS. PARFITT: I will just note that, on
- 18 pages 194 all the way through, there's a significant
- 19 discussion of the Cramer 2016 article in the first
- 20 deposition in 2019.
- 21 MR. MARTIN: I am aware it was discussed
- 22 in the first deposition. I will keep this very
- 23 short. I want to talk about specifically one
- 24 sentence that is in the 2023 expert report.
- MS. PARFITT: Very good. I appreciate

- en 1 classified controls fell to 82 percent or 18
  - 2 percent.

11

- 3 Q. I guess my question is about your
- 4 understanding of the term "nullified." Does it mean
- 5 the risk ratio would be 1.0, or does it mean the
- 6 risk ratio would be statistically insignificant? Or
- 7 does it mean something else?
- 8 A. I mean, it means an odds ratio would be
- 9 statistically insignificant.
- 10 Q. But it could still be elevated over 1.0?
  - MS. PARFITT: Objection. Form.
- 12 A. Let me just --
- 13 Q. I'll strike the question.
- 14 So let's look at the portion of Cramer that
- 15 you just quoted, which is beginning on page 341, the
- 16 final paragraph.
- 17 A. 341. Yes.
- 18 Q. Okay. "Addressing recall bias, we
- 19 conducted a sensitivity analysis that assumed truly
- 20 nonexposed cases and controls were accurately
- 21 classified as unexposed, i.e., specificity 99
- 22 percent."

1

- 23 Do you know whether that assumption, that
- 24 all truly nonexposed cases were correctly
- 25 classified, is a realistic one?

- 1 that. Thank you.
- 2 (2016 article by Daniel W. Cramer, et
- 3 al., Exhibit 15, marked)
- 4 MR. TISI: Remind me the exhibit. I
- 5 apologize.
- 6 MR. MARTIN: 15.
- 7 MR. TISI: Thank you.
- 8 A. Which page?
- 9 Q. Let's look at 12, page 12 of your
- 10 supplemental expert report.
- 11 A. Yes.
- 12 Q. In that list of bullets, it's the fourth
- 13 bullet --
- 14 A. Yeah.
- 15 Q. -- "Cramer, et al. included an 18 percent
- 16 buffer to account for recall bias before nullifying
- 17 their study results." When you say "included an 18
- 18 percent buffer," do you mean -- well, what do you
- 19 mean by that?
- 20 A. Yeah. So they have a "discussion" section
- 21 where they talk about -- let's go to the
- 22 "discussion" section. Starting from 341, addressing
- 23 recall bias, we conducted sensitivity of the
- 24 analysis, and then the odds ratio of 133 -- 1.33
- 25 would be nullified if the sensitivity of correctly

- MS. PARFITT: Objection. Form.
- 2 A. Yeah. I mean, it is to the extent that why
- 3 would nonexposed people recall talc exposure. It is
- 4 a reasonable assumption.
- 5 Q. Okay. Do you know if it's empirically
- 6 realistic?
- 7 MS. PARFITT: Objection. Form.
- 8 A. I don't understand that word. My English
- 9 is poor. What is "empirically realistic"? Is it
- 10 reasonable, unreasonable?
- 11 Q. Do you know if there are any data on the
- 12 reliability of recall?
- 13 A. Yeah. We were looking at that data, and we
- 14 just looked at Exhibit 13. And they said, you know
- 15 --
- MS. PARFITT: Could you identify the
- 17 article? O'Brien?
- 18 A. O'Brien. And they said classification of
- 19 ever use of feminine genital products may be
- 20 recalled with good -- I mean, I don't know the
- 21 numbers there, but they can recall with good
- 22 consistence. I have no reason to suspect that the
- 23 assumption that Dr. Cramer makes is suspect.
- 24 MS. PARFITT: Dr. Singh, if I can just
- 25 ask one thing -- and Mr. Martin. For the court

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- 1 reporter, when you start talking fast when you're
- 2 reading an article, she may not catch the words
- 3 you're reading from the article.
- 4 MR. MARTIN: Please, if anyone is
- 5 talking too quickly and you're not getting it down,
- 6 please let me know.
- 7 Q. Well, let's look at the next clause in the
- 8 Cramer article.
- A. Sure.
- 10 Q. The next assumption that Dr. Cramer makes
- 11 is "Truly exposed cases were also correctly
- 12 classified, sensitivity 99 percent." Do you assume
- 13 -- do you know whether that's a realistic
- 14 assumption?
- 15 MS. PARFITT: Objection. Form.
- 16 A. I mean, I don't see data elsewhere to
- 17 support that it is otherwise.
- 18 Q. Okay.
- 19 A. I mean, you know, it -- 99 percent, 98
- 20 percent, I don't see data elsewhere.
- Q. So you don't know one way or another?
- 22 A. Yeah. I mean, that's an assumption. And,
- 23 you know, it's a reasonable assumption.
- 24 Q. Okay. Next sentence, "The OR of 1.33 in
- 25 our study would be nullified if the sensitivity of
  - Page 131
- 1 correctly classified controls fell to 82 percent or
- 2 18 percent misclassification." That's what you're
- 3 basing your 18 percent buffer on?
- 4 A. Exactly.
- 5 Q. Okay. Do you know if 18 percent is a
- 6 reasonable estimate of misclassification?
- 7 A. I think they cite, you know -- they go to
- 8 other studies of -- at that time at least. You
- 9 know, they go to other studies and say "Well, let's
- 10 look at, you know, assumptions about control
- 11 classification."
- 12 And I think they have it about -- they talk
- 13 about they found an age-adjusted OR for breast
- 14 cancer -- just below that line -- of 1.42 associated
- 15 with 30 or more grams from the prospective data
- 16 compared to 1.33.
- 17 So I think, they're using that, this change
- 18 would occur if the sensitivity of controls correctly
- 19 used drop to 1 percent or 9 percent; this suggests
- 20 some degree of misclassification but not as great as
- 21 80 percent required to nullify.
- Q. That section that you just read is about
- 23 the relationship between breast cancer and alcohol?
- 24 A. Yes.
- 25 Q. Okay.

- 1 A. A lifestyle variable and cancer.
  - Q. But to be clear, it's about alcohol, not
  - 3 about cosmetic use.
  - 4 A. That is correct.
  - 5 Q. Okay. And to go in between where you read
  - 6 and I read, the sentence starting with
  - 7 "Unfortunately," "Unfortunately, there are no
  - 8 external records to validate talc use reported by
  - 9 study participants to assess whether this degree of
  - 10 misclassification is reasonable." Are you aware of
  - 11 any external records that -- any such external
  - 12 records?
  - MS. PARFITT: Used by the investigators
  - 14 in this study?
  - 15 MR. MARTIN: No.
  - 16 Q. Are you aware of any such external records
  - 17 that have come into existence since 2016?
  - 18 MS. PARFITT: Objection.
  - 19 A. Well, yeah. I mean, we discussed the
  - 20 Sister Study that, you know, assessed. But it
- 21 doesn't assess whether this degree of --
- 22 Q. Okay.
- 23 A. I mean, I saw the other Goodman study,
- 24 which talks about different misclassifications. But
- 25 I'm not sure that, you know -- we can discuss it --
- 1 whether that's reasonable. It has two, you know --
- 2 Q. You can probably conduct this deposition by
- 3 yourself because that's what I want to get at right
- 4 now.
- 5 MR. MARTIN: If we can mark Goodman
- 6 2024.
- 7 (2024 article by Julie E. Goodman, et
- 8 al., Exhibit 16, marked)
- 9 Q. All right. So I have had marked as Exhibit
- 10 16 Julie Goodman, et al., "Quantitative recall bias
- 11 analysis of the talc and ovarian cancer
- 12 association." This study was published in 2024.
- 13 So I assume -- well, so it was not,
- 14 obviously, in your expert report. But it was
- 15 produced to us on Monday by your lawyers or by
- 16 plaintiffs' lawyers. You've -- you're familiar with
- 17 this article?
- 18 A. Yes. I have had a chance to read it.
- 19 Q. And one of the things that -- well, the
- 20 thing this article does is to evaluate the possible
- 21 effects of recall bias on the Cramer study we just
- 22 looked at. Right?
- 23 A. Sure.
- Q. If you can turn to page 2 -- and I'll try
- 25 to get there. If you could look at the second

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1 column of page 2 beginning "Of these studies." And

- 2 if you can read down there for the next two
- 3 paragraphs, and I'll ask you some questions about
- 4 it.
- 5 A. Which one? The second column?
- 6 Q. Second column, the first two paragraphs of 7 the second column.
- 8 A. "In the published case control studies on 9 talc"?
- 10 Q. Yes. Correct.
- 11 A. Okay. Of these studies, only Cramer
- 12 conducted a recall bias and so did (verbatim) using
- 13 point estimates of sensitivities and specificity
- 14 rather than distribution. The investigators
- 15 recalculated the ORs assuming 99 percent recall in
- 16 cases and 99 -- and 82 percent recall specificity
- 17 and sensitivity in controls using the assumptions
- 18 the OR was 1.
- 19 Q. Would you agree with me that what the
- 20 authors are saying here is that, using different
- 21 assumptions than Dr. Cramer, that they produced
- 22 further attenuated results?
- 23 A. I haven't even read that. Yeah. But in
- 24 this analysis -- but I have my, you know -- since I
- 25 reviewed it and it came out in '24, I have my
  - Page 135

- 1 opinions on it.
- 2 Q. So let me ask you. How does this paper
- 3 affect your opinions of Cramer 2016?
- 4 A. Yeah. I will provide those opinions.
- 5 First of all, you know, I reviewed it. There are
- 6 several considerations in this paper. So the
- 7 question is, when they are doing these recall bias
- 8 analysis, where are they getting the numbers from?
- 9 They're getting it from the Sister Study,
- 10 sensitivity, spes -- that's one. And we discussed
- 11 the issues with that.
- 12 Then they are quite explicit that all their
- 13 Analysis D, Scenario 3, Scenario 4, Scenario 5 are
- 14 -- none of them adjust for any confounders. So this
- 15 is all unadjusted analysis. So, again, if
- 16 confounding is an issue in case control studies, I
- 17 don't know what weight to put on the analysis when
- 18 they are all unadjusted.
- 19 Q. Do you know whether adjustment for
- 20 confounding would increase or decrease the
- 21 association?
- A. I don't know here. You know, I don't know.
- 23 So they state that these are unadjusted. And
- 24 perhaps, even more importantly, the method that they
- 25 use is known as a triangular distribution. We chose

- 1 a triangular distribution. In the first column in
- 2 that page, they talk about a triangular distribution
- 3 because it is an ideal distribution where the only
- 4 data on hand are the maximal, minimal values and the
- 5 most likely outcome.
- 6 That is not entirely correct. You have
- 7 maximal and minimal. But you also have median or
- 8 mode. And in this case, you know, if you use a
- 9 triangular distribution versus other distributions
- 10 like port (verbatim) or others, triangular
- 11 distributions give weights to the tails. So that's
- 12 why their confidence was wider.
- Other ways to analyze this data using other
- 14 distributions would give much more curve than --
- 15 give weight to the shoulders. So I don't agree with
- 16 their analysis.
- 17 Q. You said it would give different confidence
- 18 intervals. Would it give a different point
- 19 estimate?
- 20 A. Yes. Yeah. I mean, the shapes are
- 21 different.
- Q. Okay. Let's move on to the next exhibit,
- 23 which is O'Brien 2020.
- MR. MARTIN: Actually, before we do
- 25 that, can we look at the Cramer study one more time?
- Page 137
- 1 MS. PARFITT: Cramer '16?
  2 THE WITNESS: Which is what number?
- 3 MS. PARFITT: 15. It's No. 15.
- 4 Q. Can we look at Table 2?
- 5 A. Yes.
- 6 Q. Do you see that they -- in this case, they
- 7 separately calculated odds ratios for hysterectomy,
- 8 for intact or nonintact genital tracts?
- 9 A. Yes.
- 10 Q. Okay. And do you see that the point
- 11 estimate for women who have had hysterectomy or
- 12 tubal ligation is higher than the point estimate for
- 13 women who have not?
- MS. PARFITT: I'm going to object. This
- 15 specific exact question was asked on page 196 of his
- 16 2019 deposition, I mean, down to the page number,
- 17 carrying over from the bottom of page 337 over to
- 18 338.
- 19 And the question was about tubal
- 20 ligation and hysterectomy. The question was about
- 21 the protective or lack thereof nature of those
- 22 diseases -- of that process.
- MR. MARTIN: Can we go off the record
- 24 for a moment?
- MS. PARFITT: Yes.

Page 138 Page 140 1 (A break was taken) 1 MR. MARTIN: Understood. 2 MR. MARTIN: Back on the record. Let's 2 Q. Can you look at the first sentence of the 3 "results" section in the abstract on the first page. 3 move on to O'Brien 2020, which postdates your most 4 recent deposition and report, and which we can mark 4 What's the sample size for this study in terms of 5 as Exhibit 17. 5 number of women? (2020 article by Katie M. O'Brien, et 6 A. 252, 745. 6 7 al., Exhibit 17, marked) Q. Okay. And it talks about something called 8 "person years." You understand that to be -- well, A. Do you have the supplement tables for this? Q. Not in this document. I believe I have 9 what do you understand person years to be? 10 them elsewhere. 10 A. Yeah. It's exposure time, you know, A. Can I use my copy of supplements? 11 follow-up during that study period. 12 Q. What is the number of person years at issue Q. Sure. 12 13 MS. PARFITT: Yes. 13 in this study? 14 MR. MARTIN: Yes. So this --14 A. 3.8 million. 15 MS. PARFITT: Give him one second here. 15 Q. Okay. Can we turn to Table 2, which is on 16 Okay. Good. Thank you. 16 page 53? Q. We talked about Dr. O'Brien and 17 A. Sure. 17 18 Dr. Wentzensen earlier. You agree that they're 18 MS. PARFITT: Just to be clear, not the 19 well-regarded? 19 supplemental table but --20 A. I don't know if they are well-regarded. We 20 MR. MARTIN: Correct. On page 53 of the 21 talked about that they worked for, you know, NIEHS 21 primary article. 22 Yeah. I have nothing against scientists, you know, 22 MS. PARFITT: I'm sorry about that. I'm 23 whether -- Dr. Cramer is well-regarded too. He's 23 sorry. Okay. 24 24 done tons of studies on ovarian cancer. Q. At the bottom of the first half of this Q. This article was published in JAMA. Are 25 table, they have a pooled estimate for all women. 25 Page 139 Page 141 1 you familiar with that journal? 1 Do you see that? A. I've published in it. So I'm quite A. That is correct. 3 familiar with it as you can see in my --Q. What's the confidence interval on that Q. And I hope you would agree with me it's a 4 pooled estimate? 5 prestigious journal. A. .99 to 1.17. A. Yes, it is. Q. Would you agree with me that, as 7 Q. You've published in it, you said. 7 traditionally understood, that is not statistically 8 A. Yes. Many times. 8 significant? Q. Do you read it? 9 MS. PARFITT: Objection. Misstates the 10 A. Yeah. I read it every week. 10 evidence and his testimony. Q. Would you agree with me that none of the A. Well, Dr. O'Brien herself in subsequent 12 authors here, to your knowledge, are experts on 12 interpretations has concluded that there's a 13 either side of this litigation? 13 positive association between talc and ovarian cancer A. No. They're government -- I mean, as far 14 without any qualifications about patent or nonpatent 15 as I'm aware, they are, you know, employees --15 tubes. MS. PARFITT: I didn't get to interpose 16 Q. If you could just focus on the question I 17 an objection. I'm going to object. You may 17 asked ---18 certainly answer. 18 A. Sure. 19 A. I'm not aware of their involvement. That's 19 Q. -- which is would you agree that a 20 all. 20 confidence interval that crosses 1 at a 95 percent 21 21 value is not, as traditionally understood, Q. Okay. 22 MS. PARFITT: Zack, I'm not being 22 statistically significant? 23 difficult. I just don't know who you all are going 23 MS. PARFITT: Objection. Completely 24 to be submitting in May. Many of these people could 24 misstates the state of science and his expert 25 show up. 25 opinions.

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- A. Yeah. Can you repeat it? I'm sorry. I'm 1
- 2 trying to understand and answer.
- Q. What do you understand -- you'd agree this
- 4 confidence interval -- this 95 percent confidence
- 5 interval crosses 1.0.
- A. That is correct.
- 7 Q. Okay. You'd also agree that all of the --
- 8 in each -- the confidence interval for each of the
- 9 individual cohorts crosses 1.0.
- A. That is correct.
- Q. Okay. You'd also agree that, for one of
- 12 the individual cohorts, the point estimate is below
- 13 1.0.
- 14 A. We should discuss that cohort because the
- 15 median follow-up time in that is 3.8 years, which is
- 16 not etiologically relevant for ovarian cancer. We
- 17 discussed person years. But we have 2168 with
- 18 ovarian cancer, where in the case control we have
- 19 15,000. So, yes, we should look at that. But we
- 20 also need to look at where are those numbers coming
- 21 from.
- 22 Q. Dr. Singh, I appreciate that you need to
- 23 give context. I'd appreciate it if you could focus
- 24 on the answer to my question because we have limited 24
- 25 time.

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- A. Right. I have to give context. I cannot 1
- 2 answer questions without context.
- 3 Q. Would the limited follow-up explain why the
- 4 point estimate is below 1.0?
- A. Yes.
- Q. How so?
- 7 A. Because they would not have sufficient
- 8 number of cases. You know, we -- they don't have
- 9 etiologically relevant exposure periods. You know,
- 10 three years of follow-up to really detect ovarian
- 11 cancer?
- 12 I mean, I don't think -- in my analysis,
- 13 this study should not have been -- you know, is not
- 14 really informative on the association. And,
- 15 actually, if you look at the ones that you were
- 16 pointing out -- the pooled hazard ratios -- the
- 17 confidence intervals for that are so wide that it's
- 18 just contributing very little information and weight
- 19 to the analysis.
- 20 These results that you see here, they are
- 21 driven by the NHS and WHI-OS. I can examine the
- 22 confidence, then tell you. The NHSII and VI are not
- 23 driving any of these results.
- 24 Q. The study with a 3.8-year follow-up is the
- 25 NHSII?

- A. That is correct. 1
- 2 Q. That study is not driving the pooled
- 3 estimate?
- 4 A. That is correct.
- 5 Q. Can we turn to page 3 on Table 55? Looking
- 6 at the top of Table 3, you can see that the authors
- 7 here looked at different levels of use.
- A. Yeah. They looked at, you know, frequency
- 9 and duration of use.
- 10 Q. Okay. Looking at long-term use for the
- 11 "all women" group, can you tell me what the adjusted
- 12 hazard ratio and confidence interval is?
- A. Yeah. I'll provide that and also provide
- 14 what they mean by "long-term use." So the hazard
- 15 ratio -- adjusted hazard ratio, if I'm correct, is
- 16 1.01, .82 to 1.25. So, again, NHS has no data on
- 17 long-term use.
- 18 The only three studies that provide data on
- 19 long-term use are -- NHSII, VI, and WHI-OS define
- 20 very differently. "Long-term use" is defined in
- 21 NHSII as at least weekly for 20 years. In the
- 22 Sister Study, "long-term use" is defined as perineal
- 23 use at ages 10 to 13 and in the last 12 months.
  - And in the WHI study, "long-term use" is
- 25 defined as 20 or more years for any of the three

1 questions. So what is long-term use?

- Q. Two of the three studies you mentioned
- 3 defined it as 20 or more years.
- A. Yeah. But they ask different sets of
- 5 questions. One of them even asked questions about
- 6 -- if you look at the Sister Study questionnaire, it
- 7 asks about, during the ages of 10 to 13, how often
- 8 did you apply. And the options were "sometimes,"
- 9 "frequently," "don't know." And then they had a
- 10 second about in the past 12 months.
- 11 In fact, they are incorrect in their
- 12 exposure classification because they say "more than
- 13 five times per month." If you look at Chang and the
- 14 original Sister Study, it was more than five times
- 15 per week, if I'm correct.
- Q. The question was not about frequency. It
- 17 was about length of use. There is a frequency
- 18 number later, but let's focus on the length of use
- 19 number now.
- 20 A. Sure.
- 21 Q. Point estimate is 1.01. Do you believe
- 22 that shows an association?
- 23 A. I just don't -- I believe that analysis of
- 24 long-term use is flawed because of the way long-term
- 25 use data was collected. And I mean, for example,

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- 1 let's look at Sister. Long-term use, perineal use
- 2 at age 10 to 13 years, last 12 months. What
- 3 happened to that whole --
- 4 Q. You've made your opinion clear. I'm simply
- 5 asking whether you believe a 1.01 hazard ratio
- 6 represents an association.
- 7 A. Not in this context.
- 8 Q. Okay. Thank you. You'd agree that the
- 9 1.01 point estimate here is lower than the point
- 10 estimate for all users that we discussed earlier.
- 11 MS. PARFITT: Objection to form.
- 12 A. Which was one -- which one? The overall?
- 13 Q. The overall.
- 14 A. Yeah. It would be. I mean, you know,
- 15 you're selecting a subsample. You have wider
- 16 confidence intervals. You've lost a study already,
- 17 which didn't collect data, which was, you know, a
- 18 study that was driving the estimates. So I don't
- 19 see it as any -- I think it's more about how
- 20 exposure was defined and measured and --
- 21 Q. Let's look at talc use for greater than one
- 22 week. What's the pooled estimate and confidence
- 23 interval there?
- MS. PARFITT: I'm sorry. Where are you?
- MR. MARTIN: I apologize. That's the

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- 1 total number of applications is probably the best 2 number.
- 3 And we know from several studies --
- 4 Penninkilampi, others -- that total number is a
- 5 better measure. Forget about the results. What is
- 6 a better measure? You can't separate use and
- 7 frequency. I mean, they have it. And even that,
- 8 they have mis-specified in how they have measured
- 9 it.
- 10 Q. Again, if you could just answer the
- 11 questions that I'm asking. Ms. Parfitt will have an
- 12 opportunity to ask you questions if you want to
- 13 clarify anything later.
- 14 You would agree that the long-term use
- 15 point estimate is lower among women with patent
- 16 reproductive tracts.
- 17 MS. PARFITT: Objection. Asked and
- 18 answered.
- 19 A. How is that lower? Is it 1.01 and 1?
- 20 Q. Yes.
- 21 A. I don't think that makes any material
- 22 difference, I mean.
- 23 Q. Okay. So Dr. O'Brien and colleagues did
- 24 not initially look at only medically confirmed
- 25 cases; is that correct?

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- 1 end of the first half of Table 3.
- 2 A. Yeah. 1.09, .97 to 1.23.
- 3 Q. Let's look at the bottom half of the table,
- 4 which is women with patent reproductive tracts.
- 5 A. Sure.
- 6 Q. Again, let's look at long-term use. What
- 7 is the adjusted hazard ratio there?
- 8 A. 1.
- 9 Q. Okay.
- 10 A. .76 to 1.32.
- 11 Q. So there's no association reported there;
- 12 correct?
- 13 MS. PARFITT: Objection. Form.
- 14 A. Yeah. But the frequent users report an
- 15 association 1.19, 1.03 to 1.37.
- 16 Q. Correct. But the long-term users, there's
- 17 no association reported.
- 18 A. Yeah.
- 19 MS. PARFITT: Objection.
- Q. That's a lower point estimate, again, than
- 21 the long-term users -- than "all women" long-term
- 22 users?
- A. I mean, I think we are talking about dose,
- 24 you know. We have to talk about what is an
- 25 appropriate measure of dose. It is, you know --

- 1 A. Yeah. Show me the section. I have vague
- 2 recollection, but you have to point me out where.
- 3 Q. Well, I'll point you to Table 4, which is
- 4 on the next page, which is a subset of medically
- 5 confirmed cases. Do you see that?
- 6 A. Yes.
- 7 Q. Okay. Let's look at all medically
- 8 confirmed cases, ever use, top left column. What's
- 9 the hazard ratio there?
- 10 A. Hazard ratio -- I mean, if you want to just
- 11 have me read things, yes, it is 1.05, .96 to 1.16.
- 12 Q. Would you agree that -- do you believe a
- 13 1.05, 0.96 to 1.16 confidence interval demonstrates
- 14 an association?
- 15 MS. PARFITT: Objection. Asked and
- 16 answered.
- 17 A. Depends on the context. You know, we have
- 18 many associations, that, you know, maybe 5 percent
- 19 is a protective effect, you know, diets, fruits,
- 20 vegetables, you know, and even a 10 percent
- 21 increased risk is -- so it really depends on the
- 22 context of, you know, and what else do we know about 23 that.
- Q. So a few moments ago, you said you didn't
- 25 think there was a material difference between 1.01

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- 1 and 1.0.
- 2 A. Yeah.
- 3 Q. There may be a material difference between
- 4 1.05 and 1.0. How do I know where you draw the line
- 5 here?
- 6 MS. PARFITT: Objection. Misstates the 7 testimony.
- 8 A. I'm not parsing out 1 and 2 and 3. I mean,
- 9 that's not what I'm saying. I'm saying that to the
- 10 -- in terms of a material difference, it is, like,
- 11 what is the question you're trying to answer right
- 12 there. And remember, there are different set of
- 13 adjustments. So the sample size has changed.
- 14 Obviously, the point estimates will change.
- 15 Q. Okay.
- 16 A. Exposure metrics have changed. You have
- 17 "ever," "long-term," "frequent."
- 18 Q. But you would agree with me that the hazard
- 19 ratio among medically confirmed cases was attenuated 19
- 20 from the 1.09 we talked about earlier.
- 21 A. Yeah. Because --
- 22 MS. PARFITT: Objection.
- 23 A. -- the numbers of cases declined. Number
- 24 of cases declined. So it went from already low,
- 25 2,168, to now even lower, 1800 cases. Of course,

- 1 "limitations," so "The strengths of this study."
- 2 A. That's 57.
- 3 Q. You're correct, and I'm wrong. Thank you.
- 4 Do you see where I intend to be?
- 5 A. Yes.
- 6 Q. Okay. "The strengths of the study were
- 7 long" -- excuse me -- "large sample size and long
- 8 follow-up time." Do you agree that those are
- 9 strengths of the study?
- 10 A. I think as compared to the previous cohort
- 11 studies, yes, but not sufficient enough to detect
- 12 cancer like ovarian cancer related to talc. Yes,
- 13 compared to the initial cohorts, they have increased
- 14 the sample size.
- 15 Q. Did you mention that in your expert report?
- 16 A. I don't recall what I mentioned. But,
- 17 yeah, I mean, I did talk about their -- I'll have to
- 18 go and look at it.
  - Q. Okay.
- 20 A. Give me one second. I did not mention that
- 21 specific strength. But I also mentioned that
- 22 strengths are noted, they're less prone to recall
- 23 and recall bias remains a concern. But I did not
- 24 mention that specific strength.
- Q. Okay. Would you agree with me that one of

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1 you know, these could be attenuated.

- 2 Q. Why would a smaller number of cases reduce
- 3 the hazard ratio?
- 4 A. Because of power.
- 5 Q. Okay. Power would increase the size of the
- 6 confidence interval?
- 7 A. And can lower the point estimates because
- 8 you are unable to detect an association. Either
- 9 way.
- 10 Q. Okay. Could it also raise the point
- 11 estimate?
- 12 A. Lower power?
- 13 Q. Yes.
- 14 A. How would it raise the point estimate?
- 15 Q. Is your testimony that it is impossible for
- 16 lower power to raise the point estimate?
- 17 MS. PARFITT: Objection. Asked and 18 answered.
- 19 A. If a study is statistically under power,
- 20 what it does, it gives you a more imprecise
- 21 confidence interval.
- Q. Let's look at the "discussion" section.
- 23 Let's look at page 58.
- A. The reference?
- Q. This is the last paragraph before

1 your criticisms of the cohort studies that preceded

- 2 O'Brien was insufficient statistical power?
- 3 A. That is correct.
- 4 Q. And another criticism was insufficient
- 5 follow-up time.
- 6 A. That is correct.
- 7 Q. Okay. Let's look at page 50 of O'Brien.
- 8 A. 58?
- 9 Q. 50. I apologize.
- MS. PARFITT: Let us know if you need to
- 11 take a break. Not in the middle of a question,
- 12 though.
- 13 Q. Do you see the last paragraph of the
- 14 introduction -- last sentence of the introduction?
- 15 A. Yeah.
- 16 Q. "Incorporate additional data, including
- 17 additional cases and longer follow-up time."
- 18 A. Yes.
- 19 Q. Do you know how many years of follow-up
- 20 time were added for each of the underlying cohorts
- 21 in the O'Brien 2020 data?
- A. I mean, not specifically. But I think
- 23 Table 1 provides that, you know.
- 24 Q. Yeah.
- 25 A. If we can go there and talk about it.

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- 1 MR. MARTIN: Can we take a break and
- 2 then go there and talk about it? Off the record.
- 3 (A break was taken)
- 4 MR. MARTIN: Let's go back on the record
- 5 and mark a new exhibit, which is your 2018 expert 6 report.
- 7 (2018 report of Sonal Singh, M.D.,
- 8 M.P.H., Exhibit 18, marked)
- 9 A. Back with O'Brien later?
- 10 Q. We're going to go back and forth. So if
- 11 you can keep O'Brien up, that would be great.
- 12 A. Sure.
- MR. TISI: You mean old report, new
- 14 report or --
- 15 MR. MARTIN: Potentially all three. I'm
- 16 sorry the table is so small.
- MR. TISI: No. It's okay. You had
- 18 nothing to do with the table. I just wanted to make
- 19 sure --
- 20 MR. MARTIN: I did not, no.
- 21 Q. Look at page 49 of your 2018 report.
- 22 A. Yeah.
- Q. So this is the Women's Health Initiative
- 24 study reported in Houghton. Do you see where you
- 25 noted that the study had only 429 ovarian cancer

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- 1 limited follow-up. And then even for WHI, if you
- 2 look at the footnote to that table, they say that
- 3 pool's baseline oophorectomies were not recorded.
- 4 So we don't know what happened to women who
- 5 got an oophorectomy after exposure and developed
- 6 ovarian cancer so -- because they were not
- 7 collecting data on ovarian cancer -- oophorectomy.
- 8 Q. They were collecting data on ovarian
- 9 cancer.
- 10 A. Yeah. But some of these oophorectomies
- 11 could be due to ovarian cancer. That is the same
- 12 case with NHSII.
- 13 Q. Okay.
- 14 A. Because data were reported in two-year
- 15 cycles, we did not sense for oophorectomy that
- 16 occurred after 2013, whereas NHS and Sister did
- 17 sense it.
- 18 Q. So let's talk about NHSII. That's entirely
- 19 new data reported for the first time in O'Brien.
- 20 A. Yes.
- 21 Q. Okay. And then NHSI, which you talked
- 22 about in your initial report on pages 47 and 48 --
- 23 A. Yes.
- Q. Okay. Initially, there were 307 cases of
- 25 ovarian cancer.

- 1 cases?
- 2 A. Yes.
- 3 Q. Do you see at the beginning of the second
- 4 paragraph on page 50 where you noted it as 12 --
- 5 there were 12.4 mean years of follow-up?
- 6 A. Where is that? I'm sorry.
- 7 Q. The beginning of the first paragraph on
- 8 page 50 of your 2018 report.
- 9 A. Okay. 50. Right?
- 10 Q. 50.
- 11 A. Yeah.
- 12 Q. Okay. So let's compare that to the nurses
- 13 -- excuse me -- the Women's Health Initiative study
- 14 in O'Brien Table 1.
- 15 A. Sure.
- 16 Q. Now, 659 cases and 17.4 average years of
- 17 follow-up. Do you see that?
- 18 A. That is correct.
- 19 Q. Okay. So substantially more on both --
- 20 substantially more cases and longer follow-up.
- 21 A. Yes. The number of cases has increased.
- 22 Follow-up has increased. But there is, you know, 23 obviously -- if you only look at the Women's Health
- 24 Initiatives, that's true.
- 25 But NHS is, you know -- NHSII has very

- 1 A. Yeah.
- Q. And now there are 1,258.
- 3 A. That is correct.
- 4 Q. So about -- more than triple -- more than
- 5 quadruple, actually.
- 6 A. Yeah. That is correct. But we have to
- 7 examine that. The analysis in that study, 2000,
- 8 page 47 -- if you go to page 48, they report there
- 9 was an increase -- all the analyses adjusted for
- 10 tubal ligation. Now here, we have analysis which
- 11 interact by, you know, age adjusted for -- after
- 12 adjusting for co-variants.
- 13 So tubal ligation, if you look at page 40
- 14 in the first line, tubal ligation and parity were
- 15 confounders in that analysis.
- MR. MARTIN: Let's go off the record.
- 17 There's a knock at the door.
- 18 (A break was taken)
- 19 MR. MARTIN: Back on the record.
- 20 Q. I believe I asked you about the increased
- 21 sample size in the Nurses' Health Study reported in
- 22 O'Brien. And you agreed that it was more than
- 23 quadruple the size of the initial Nurses' Health
- 24 Study in terms of cases.
- 25 A. Yes. And I also pointed out the specific

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- 1 issue that the first Nurses' Health Study adjusted
- 2 for the confounder of tubal ligation, whereas here,
- 3 now they have started to look at -- in fact, all the
- 4 three studies -- Sister and WHI also -- adjusted it
- 5 as a confounder. So now, you know, there's a
- 6 separate analysis. So it's something to note, that
- 7 when we are looking at these numbers, what are the
- 8 implications of that.
- Q. Those numbers wouldn't -- the -- I'm trying
- 10 to get at the power of the study. Whether it
- 11 adjusted for tubal ligation would not address the
- 12 power of the study, would it?
- 13 MS. PARFITT: Objection.
- 14 A. It would. It would. Because -- why?
- 15 Because power also depends on confounders. Right?
- 16 Power is -- you're talking about unadjusted power
- 17 versus adjusted power. Powers is -- numbers is one
- 18 issue. But what are the other issues?
- You know, we've talked about confounding
- 20 and recall bias. So power is just you -- obviously
- 21 -- number is one issue. The other is etiologic
- 22 follow-up time. For example, NHSII, you add this to
- 23 million-year follow-up time. I'm not sure any of it
- 24 has etiologic relevance. 3.8 years of follow-up,
- 25 you present that to an ovarian cancer researcher and

- 1 increased follow-up time.
  - MS. PARFITT: Right. If you look at
  - 3 page 16 of your report.
  - A. Yeah. So, I mean, not specifically for
  - 5 each of the studies. But if you go to page 16, I do
  - 6 talk about follow-up in the context of discussion of
  - 7 these studies, not specifically in that section on
  - 8 O'Brien.
  - 9 But this is where I'm discussing in the
  - 10 section on the Health Canada reports assessment of
  - 11 these studies where they talk about follow-up time.
  - 12 Only four years of follow-up -- the NHSII was added
  - 13 to the O'Brien analysis, and only four years of
  - 14 follow-up was added.
  - 15 Q. When you're talking about these studies --
  - 16 when you're talking about the Gonzalez study in the
  - 17 second paragraph under "cohort studies" --
  - 18
  - 19 Q. -- and you note a median of 6.6 years of
  - 20 follow-up, that's the initial Gonzalez study;
  - 21 correct?
  - 22 A. That is true.
  - 23 Q. Not the updated version, O'Brien?
  - 24
  - 25 Q. Similarly, when you talk about Houghton in

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- 1 -- it's not relevant. So it's not just the years.
- 2 It's -- the question is what is relevant years?
- And I said, you know, NHS and WHI are
- 4 informative. NHSII is really not informative. I'm
- 5 not even sure why one would include a study of
- 6 limited follow-up in the same analysis.
- 7 Q. You mentioned earlier that you thought
- 8 NHSII was not a major contributor to the pooled
- 9 estimate.
- 10 A. Yes. Q. Okay.

11

- 12 A. It isn't.
- Q. Okay. Did you note the increased follow-up
- 14 time in these studies anywhere in your 2023 report?
- 15 A. Let me take a look. Please give me one 16 second.
- 17 MS. PARFITT: Can I direct him to pages?
- 18 MR. MARTIN: Yes.
- 19 MS. PARFITT: Page 16, you're talking
- 20 about your cohort studies, Doctor, if that helps
- 21 you, page 16.
- 22 THE WITNESS: No.
- 23 MS. PARFITT: I think the question was
- 24 follow-up time. Is that right?
- 25 MR. MARTIN: Whether you noted the

- 1 the next paragraph, 12.4 --
- A. That's the initial. And I think those are
- 3 the references cited there.
- Q. Okay. Can we skip back to page 11 of your
- 5 report?
- MS. PARFITT: '23 report? 6
- 7 MR. MARTIN: '23 report.
- 8 MS. PARFITT: Thank you.
- 9 Q. This gets back to what we were talking
- 10 about earlier about statistical significance in
- 11 P-values. It's the second-to-last paragraph of
- 12 page 11. "The authors interpreted an HR of 1.08
- 13 with a lower bound of 0.99 as being no evidence of
- 14 an association, which is inconsistent with the
- 15 American Statistical Association statement."
- 16 So I take it that you consider a 1.08 HR
- 17 with a lower bound of .99 to represent an
- 18 association?
- 19 A. Not only I do. They do, too, in their
- 20 subsequent -- you know, in the response to the
- 21 letter. They just state that this -- and I'm going
- 22 to read it --
- 23 MS. PARFITT: "They," you mean?
- 24 A. Dr. O'Brien, et al. Obviously, I do but --
- 25 Q. We're going to get to the responses to the

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- 1 letter by both Dr. O'Brien as well as Drs. Cramer
- 2 and Harlow in a little bit.
- 3 My question is whether you consider an HR
- 4 of 1.08 to be a strong association.
- 5 MS. PARFITT: Objection. Form.
- 6 A. Yeah. So, again, I think of strength not,
- 7 you know -- and I know some people -- and I may have
- 8 used terms like "moderate" and "strong" in the past.
- 9 But, you know, "strong" is more in the appropriate
- 10 context. I mean, is it in the appropriate public
- 11 health context and for an individual patient?
- 12 If there is a preventible risk factors --
- 13 for example, let's say reducing cancer by eating
- 14 fruits and vegetables -- 1.09 would be very strong.
- 15 Q. In terms of evaluating whether an observed
- 16 association is causal in the first instance, do you
- 17 consider a 1.08 hazard ratio to be strong?
- 18 MS. PARFITT: Objection. Form.
- 19 A. I wouldn't even -- I wouldn't even, you
- 20 know -- I don't -- I wouldn't say that that's what
- 21 -- I wouldn't start -- I would just interpret it in
- 22 the context of other data, you know. I can't look
- 23 at just one piece of information, 1.09. What's the
- 24 other context? Is there a biologic plausibility?
- 25 Is there dose response? I don't think you can look

- 1 population is different. We have -- you know, if
  - 2 you look at NHSII and Sister Study, these are
  - 3 younger -- you know, younger women. You know, some
  - 4 of the recruitment was for oral contraceptive use.
  - 5 Tubal ligation occurs at different ages.
  - 6 Hysterectomy occurs at different ages. So the --
  - 7 where they impact hazard ratios, you know, you can't
  - 8 compare one study to the other.
  - Q. Okay. So let's flip to page 11, the first
  - 10 full sentence, "Other epidemiologic studies have
  - 11 noted a significantly increased risk of ovarian
  - 12 cancer with no tubal ligation compared to those with
  - 13 tubal ligation." Would you agree that some studies
  - 14 have noted the opposite of that?
  - 15 A. That is correct.
  - 16 Q. Let's turn back to page 52 of the O'Brien
  - 17 study. When you get there, it's going to be the
  - 18 final paragraph of page -- of the first column.
  - 19 A. Is it, like, a text or --
  - 20 Q. Yes. It's text. It should start with the
  - 21 words "Statistical tests."
  - 22 A. The "results" section?
  - Q. No. It's right before the "results"
  - 24 section.
  - 25 A. Okay.

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- a or not
- 1 at association and say "Well, it's strong or not
- 2 strong" and consistency or inconsistency.
- 3 Q. Let's go back to page 10. This is your
- 4 discussion of the O'Brien subset involving women
- 5 with intact tubes. "However, they conducted a
- 6 prespecified analysis evaluating the risk of ovarian7 cancer among women with patent reproductive tracts.
- 8 The analysis showed a statistically significant
- 9 excess risk for ever users and never users, even
- 10 after adjustment for various risk factors."
- First of all, is access risk for ever users
- 12 and never users a typo there?
- 13 MS. PARFITT: Objection. Form.
- 14 A. Should be "versus."
- 15 Q. That's what I thought.
- 16 A. Yeah. "Versus never users." Yeah.
- 17 Q. How do you balance that result with the
- 18 result we talked about earlier from Cramer that
- 19 showed a higher odds ratio for women with a tubal
- 20 ligation or hysterectomy?
- 21 MS. PARFITT: Objection. Asked and
- 22 answered and covered in his 2018. But you may
- 23 answer.
- 24 A. Yeah. So, I mean, again, those are two
- 25 different populations. You know, Cramer's

- Q. "Statistical tests were two-sided, and the
- 2 P-value of less than .05 was considered
- 3 statistically significant. Because of the potential
- 4 for Type 1 errors due to multiple comparisons,
- 5 finding from subgroup and sensitivity analyses
- 6 should be interpreted as exploratory. All analyses
- 7 were conducted in SAS9.4."
- 8 What do you -- can you explain the concept
- 9 of multiple comparison testing?
- 10 A. Sure. Multiple testing is if, you know,
- 11 you conduct a study and you have or -- somehow you
- 12 have different questions you're trying to answer and
- 13 you do more than one analysis or 10 analysis or 15
- 14 analysis or 20, then you may want to do a correction
- 15 for that.
- Q. Is that because running more analyses
- 17 increases the possibility that one of them will
- 18 appear statistically significant by chance?
- 9 A. Yes. But in this case, the analysis that
- 20 -- was etiologically relevant and was prespecified
- 21 is not -- I know they talk about exploratory. But
- 22 they even emphasize importance -- and, again, I know
- 23 we're going to discuss in the letter -- is not
- 24 necessarily just a subgroup analysis.
- 25 Q. So let's actually turn to what you said,

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1 the exploratory discussion, which is on page 56.

- 2 A. Yeah.
- 3 Q. It's the middle paragraph of the second
- 4 column beginning "When restricted."
- 5 A. So it's the second text; right?
- Q. Yes. It is text, but I actually may have
- 7 the wrong place. I'm sorry. I guess I'm wrong. On
- 8 page 56. It's in text.
- 9 MS. PARFITT: I'm sorry, Zack. I'm not 10 seeing it.
- MR. MARTIN: It's halfway through the
- 12 first for -- the final paragraph of page 56.
- 13 THE WITNESS: Give me a second.
- 14 MR. MARTIN: Begins "In this analysis."
- MS. PARFITT: Do you have it now?
- 16 THE WITNESS: Yeah. Yeah. I have it.
- 17 Q. That sentence is what you mentioned
- 18 earlier. Says "This finding should be considered
- 19 only exploratory and hypothesis generating." That's
- 20 referring to the finding among women with intact
- 21 tubes; correct?
- 22 A. Yeah. No. I'm not mentioning that. I'm
- 23 going to her letter, page 2097, where she states --
- 24 Dr. O'Brien states that "Therefore, even though we
- 25 stated that findings from subgroup analysis should
  - Page 167

1

- 1 be interpreted as exploratory, we do not consider
- 2 them all equally important and agree that the
- 3 positive association among women with patent tubes
- 4 is consistent with the hypothesis that there's an
- 5 association between genital powder use and ovarian
- 6 cancer." That's in the letter that --
- 7 Q. Correct.
- 8 MS. PARFITT: Finish. That's in the
- 9 letter that what?
- 10 A. That she responded to Drs. Harlow and
- 11 others who had pointed out that.
- 12 Q. Do you believe that you are using the
- 13 subgroup analysis for patent tubes in an exploratory
- 14 and hypothesis-generating way?
- MS. PARFITT: Objection. Misstates his
- 16 testimony.
- 17 A. I am or she is?
- 18 Q. Do you believe that you are in your expert
- 19 report?
- 20 MS. PARFITT: Objection.
- 21 A. No. I'm looking at etiologically relevant
- 22 exposure. And as was done in the first three, you
- 23 know -- if you look at NHSI and, you know, WHI and 23
- 24 Sister, they were adjusting for these tubes. So
- 25 they were considering them as confounders.

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- 1 And now we know that the mechanisms --
- 2 these are the mechanisms of retrograde migration of
- 3 talc. So these are prespecified exploratory. And I
- 4 stress the word "prespecified" because they were
- 5 looking for specific mechanism.
- Q. Just, again, to get a clear record on my
- 7 question, you do not believe that you are using the
- 8 subgroup analysis in an exploratory or hypothesis-
- 9 generating way in your report.
- 10 A. I mean, I think it is a causal -- I'm not
- 11 using it as an exploratory. I'm using it as a
- 12 causal, you know, hypothesis -- causal statement
- 13 about talc and ovarian cancer. It's not
- 14 exploratory.
- 15 Q. Let's look back at your report, page 11.
- 16 A. New report; right?
- 17 Q. New report. I'm sorry. Yes.
- 18 A. Yeah.
- 19 Q. Two thirds of the way down, it says
- 20 "Inability to assess tests for patency." "The
- 21 authors acknowledged they did not perform tests for
- 22 patency, so women reported as being patent in this
- 23 analysis may not have patent reproductive tracts."
- 24 That's a concern about misclassification; right?
- 25 A. Give me a second. Okay.

- Q. Do you know how -- do you know how the data
- 2 were collected with respect to women's patency in
- 3 the underlying studies?
- 4 A. Self-reported.
- 5 Q. Self-reported. Do you believe most women
- 6 know whether they have fallopian tubes or not --
- 7 intact fallopian tubes or not?
- 8 MS. PARFITT: Objection. Form. You can
- 9 answer that.
- 10 Q. If you don't know the answer, that's fine.
- 11 A. I mean, women would know that. Yeah. But
- 12 do they report it accurately? That's two different
- 13 questions, you know. "Do they know it?" Is one
- 14 thing. "Do they report it accurately?" It's two,
- 15 you know -- two levels of questions.
- Q. Let's look at Gossett 2020. Are you
- 17 familiar with this? This is an editorial that
- 18 accompanied O'Brien in JAMA.
- 19 A. Yes.
- MR. MARTIN: Okay. We'll mark this as
- 21 an exhibit. Can we go off the record for less than
- 22 a minute while I look at my notes.
  - (A break was taken)
- MR. MARTIN: Back on the record. Let's
- 25 mark this as Exhibit 19.

2 Exhibit 19, marked)

1

(2020 Dana R. Gossett, M.D. editorial,

Q. This is the Gossett editorial we were

4 talking about before the break. All right. Can we

5 look at the second page of the editorial, which is

8 paragraph, "It is not possible to equate a patent

9 reproductive tract with exposure and a nonpatent

12 is because women who undergo tubal ligation or 13 hysterectomy and use powders in the genital area

15 only after their surgery. Do you agree with that,

A. Let me read it. Which part did you

18 mention? "Given this" -- second paragraph? Q. I will just ask it as a general question.

14 cannot be assumed to have started using the product

20 Do you agree that women may undergo a tubal ligation

21 or hysterectomy after having already used talcum

Q. So as a result, there may be women with

25 nonintact genital tracts who nevertheless have

Do you see the second sentence of that

And they go on and explain that the reason

6 page 30 of JAMA, first full paragraph?

10 reproductive tract with non-exposure"?

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1 elevated. So there's different ways to interpret

- 2 the subgroup analysis.
- Q. Just to be clear --3
- 4 A. Sure.
- 5 Q. -- is what you're saying that it could be
- 6 that both groups are at risk, or it could be that
- 7 neither group is at risk?
- A. No. I'm saying that they -- what they're
- 9 interpreting is, because there is no test for
- 10 interaction that's different, the hazard ratio, that
- 11 is statistically significantly higher for the
- 12 patent. And, you know, the hazard ratio for
- 13 nonpatent is lower and not significant. They are
- 14 interpreting -- this is overall conclusion, that
- 15 there is no demonstrable (verbatim).
- 16 My interpretation is it is entirely plausible
- 17 that the nonpatent subgroups' hazard ratios and, you
- 18 know, the hazard ratios in the patent are similar.
- 19 So I have a -- not completely -- yes, it is a
- 20 completely different interpretation. If there's no
- 21 difference, .99 -- the group in .99 is the same as
- 22 the group in the patent.
- 23 Q. Okay. And would you interpret from that
- 24 that both groups are at risk?
- 25 A. Yes. I mean, that's one plausible

1 interpretation.

2 Q. Okay.

- 3 A. I'm, you know -- I'm not saying that the
- 4 non -- but when you do tests for interaction, you
- 5 have to keep both plausible interpretations in mind.
- Q. Is it also plausible that neither group is 7 at risk?
- 8 MS. PARFITT: Objection. Form.
- 9 A. I mean, we already know that the patent is
- 10 -- patent group was increased. It is plausible that
- 11 there are no differences between the groups.
- 12 The only -- the test for interaction only
- 13 tell us, because the numbers are so reduced, that
- 14 there are no differences. The question is now you
- 15 have to bring in your understanding of biology,
- 16 retrograde migration, other studies to interpret
- 17 this. You cannot just look at P of .15 and
- 18 interpret that.
- 19 How do we interpret this data? She's -- I
- 20 don't know he or she. But Dr. Gossett is providing
- 21 one interpretation. I'm bringing another
- 22 interpretation based on biology, based on other
- 23 studies, that it is entirely plausible -- I am, you
- 24 know -- I think the association between talcum
- 25 powder products and ovarian cancer in the patent

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1 exposure to talcum powder.

A. Yes.

16 generally?

22 powder?

A. Yes.

17

23

24

- Q. Because they had that exposure before they
- 4 had surgery. Okay. If we can go down to the
- 5 sentence starting "The fact that."
- A. Yes.
- 7 Q. "The fact that there are no significant
- 8 differences in the HRs in the patent," parentheses,
- 9 "HR, 1.13, 1.01 to 1.26, and nonpatent subgroups,
- 10 .99, .86 to 1.5, confirms the overall conclusion
- 11 that there is no demonstrable statistically
- 12 significant association between the use of powder in
- 13 the genital area and ovarian cancer risk." Do you
- 14 agree with that statement?
- A. I disagree because the authors in the
- 16 response to letters also disagree with that. And,
- 17 you know, one interpretation of their tests of
- 18 interaction would be that the nonpatent subgroups
- 19 also have an increased risk because there is no
- 20 difference.
- 21 So why are we assigning the patent to be
- 22 nonsignificant and saying that the nonpatent is
- 23 driving the results? But it could be, if there's no

25 mean, that the nonpatent subgroups are also

24 difference between the two groups -- what it could

44 (Pages 170 - 173)

	5 454		D 454
1	Page 174 group is causal. It's also entirely plausible that	1	Page 176 MS DARFITT: Objection Form
	the nonpatent groups have similar risks.	$\begin{array}{ c c }\hline 1\\2 \end{array}$	MS. PARFITT: Objection. Form.  A. Give me one second to read this. No. I
3	Q. Is it plausible, or has it been	3	disagree with that.
	established?	4	Q. Do you agree that there ever is an effect
5	MS. PARFITT: Objection. Asked and	5	size below what an epidemiologist should consider
	answered.	6	important?
7	A. It is plausible. I wouldn't say that for	7	MS. PARFITT: Objection. Form.
		8	A. Epidemiologists, you know, not only
9	Q. Okay.	9	consider effect size, they need to consider bias,
10	MR. TISI: For what? I'm sorry.		confounding, you know, possibility of power and
	Continue.		sample size issues.
12	A. I would say in this study the you know,	12	So, I mean, effect size is just one aspect
	they don't establish that the nonpatent subgroups		of causal assessment. But, you know, is it a .991?
	are they do say that the overall risk is		Is it a point is it 1.1? I don't have an opinion
	increased. They don't establish that for nonpatent.		on that. But I have examples in my report of very
16	Q. Okay. The sentence that runs that		small effect sizes I'm not going to be wedded to
1	begins the end of the first column and runs into the		1.09 or 1.1 small effect sizes that are causal.
	second column, "The subgroup analysis suggesting	18	Q. Can we look back at your report, page 11?
	that women with intact reproductive tracts who used	19	MS. PARFITT: Just for the record,
	powder in the perineal area developed ovarian cancer		that's the '23 report?
	more frequently than nonusers is below the effect	21	MR. MARTIN: The '23 report.
	size that epidemiologists generally consider	22	MS. PARFITT: Thank you.
	important and should not be selectively highlighted	23	MR. MARTIN: If I say "report" without
	by the statistically unsophisticated reader as	24	qualification, I mean the 2023 report.
25	evidence of a relationship."	25	MS. PARFITT: Thank you. Okay. page
23	evidence of a relationship.		ms. Tritti III. Thaim you. Onay. page
23			
1	Page 175		Page 177
			Page 177
1	Page 175 A. I'm sorry. Where are you? First page?	1 2	Page 177
1 2	Page 175 A. I'm sorry. Where are you? First page? MS. PARFITT: Go to the next page.	1 2	Page 177 11? MR. MARTIN: Yes. "Limited statistical
1 2 3	Page 175  A. I'm sorry. Where are you? First page?  MS. PARFITT: Go to the next page.  Q. This is the second page. It's the sentence	1 2 3 4	Page 177 11?  MR. MARTIN: Yes. "Limited statistical power."  Q. "The number of cases of ovarian cancer in
1 2 3 4	Page 175  A. I'm sorry. Where are you? First page?  MS. PARFITT: Go to the next page.  Q. This is the second page. It's the sentence that spans the end of the first	1 2 3 4 5	Page 177 11?  MR. MARTIN: Yes. "Limited statistical power."  Q. "The number of cases of ovarian cancer in
1 2 3 4 5 6 7	Page 175  A. I'm sorry. Where are you? First page?  MS. PARFITT: Go to the next page.  Q. This is the second page. It's the sentence that spans the end of the first  MS. PARFITT: Back. I'm sorry. If you	1 2 3 4 5 6	Page 177 11?  MR. MARTIN: Yes. "Limited statistical power."  Q. "The number of cases of ovarian cancer in 24 case control studies N equals 13,421 is
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1 2 3 4 4 5 6 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Page 175  A. I'm sorry. Where are you? First page?  MS. PARFITT: Go to the next page.  Q. This is the second page. It's the sentence that spans the end of the first  MS. PARFITT: Back. I'm sorry. If you don't mind.  MR. MARTIN: No, please.  THE WITNESS: Sorry. I misunderstood the directions.  MS. PARFITT: No. No. No. You're right here. Right here. Starts here.  THE WITNESS: Okay.  MS. PARFITT: Then it goes up over here.  THE WITNESS: Got it. Sorry.  MS. PARFITT: Thank you.  MR. MARTIN: No problem.  Q. Do you agree  A. What is the question?  Q. Do you agree that the effect size let me start that over.  Do you agree that the difference between women	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Page 177  11?  MR. MARTIN: Yes. "Limited statistical power."  Q. "The number of cases of ovarian cancer in 24 case control studies N equals 13,421 is more than sixfold higher than the number of cases of ovarian cancer reported by O'Brien, et al N equals 2,168 demonstrating the limited power of cohort studies to detect a significant increase in risk of ovarian cancer."  So your position is that the lack of power could be a reason that Dr. O'Brien's top-line results were not statistically significant?  A. Yeah. And I'll explain it a little bit more. So power is one aspect. But why did she get their the numbers, she got more cancer there were more cancers in NHSI, more follow-up time.  There were more cancers in NHSI and some follow-up time but that was etiologically irrelevant then some more follow-up in WHI in follow-up time.  But she did not get etiologically relevant

25

Q. What do you think is a sufficient --

25 important?

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1 MR. TISI: I'm sorry. He wasn't 2 finished.

Q. I'm sorry. Please finish.

A. I'm sorry. I would have had to calculate

5 that. Post hoc power calculations are not

6 appropriate now that we have results of the study.

Q. Do you recall citing in your initial report

8 an article by Narod, "Talc and ovarian cancer,"

9 2016?

10 A. Yes. And I remember the numbers they

11 quoted about power.

12 Q. Great. So let's look back -- let's look at

13 your supplemental report, paragraph 7 or -- page 7,

14 which also sites Narod, first full sentence.

15 A. Give me a second. I'm not there.

16 Q. Are you there?

17 A. Yes.

Q. Narod, et al. estimate that upward of

19 200,000 women would have to be enrolled in a cohort 19 significance in a prospective cohort study, we need

20 study to detect an effect size of 1.2.

21 A. Sure.

Q. Do you agree that more than 200,000 women 22

23 were included in the O'Brien study?

A. O'Brien is not a single cohort study.

25 O'Brien is a pooled analysis of four different

Page 180

1 e.g., we will need to study upwards of 200,000 women

2 for ten years."

So the Narod article didn't just talk about

4 number of women. It also discussed follow-up time;

5 correct?

A. Where are you, just so that I know?

7 MS. PARFITT: Yeah. I've lost you, too,

8 Zack. I'm sorry.

MR. MARTIN: It's page 2. 9

10 MS. PARFITT: Got it.

MR. MARTIN: The first full paragraph.

12 MS. PARFITT: First full.

13 MR. MARTIN: I'm sorry. It's the final

14 sentence of that. Begins "In order to achieve."

MS. PARFITT: Right there. I was 15

16 looking at the second paragraph. I'm sorry. I'm

17 sorry.

11

18 Q. "In order it achieve statistical

20 a much larger cohort, e.g., we will need a study of

21 upwards of 200,000 women for ten years." So Narod

22 did talk about follow-up time in addition to time;

23 correct?

24 A. Sure.

25 Q. Do you know the average follow-up time in

Page 179

1 cohorts, each with different etiologically relevant

2 exposure period.

This assumes that these 2,000 (verbatim) --

4 you know, you're following these -- it's just not a

5 number. Right? It's, like, how much follow-up time

6 you're going to have. Power is not just about a

7 cohort. It's, like, how much cancer you're going to

8 have or what duration of time you're going to follow

9 them up. Yes, it has more than 200,000. But it's

10 not a single cohort study. Didn't follow them for

11 enough time.

12 Q. Let's talk about length of time followed.

13 And let's talk about the Narod article, which I will

14 mark as Exhibit 20.

15 (2016 study by Steven A. Narod,

16 Exhibit 20, marked)

Q. Let's look at the first -- the last

18 sentence of the first full paragraph on page 2, "In

19 order to achieve."

20 A. Page 2, last sentence of the --

21 Q. First full paragraph.

22 A. "Prospective observational studies"?

23 Q. "In order to achieve statistical

24 significance in a prospective observational

25 (verbatim) study, we need a much larger cohort,

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1 the O'Brien pooled analysis?

A. Yeah. Exactly. So what you're doing in

3 O'Brien is you are adding etiologically irrelevant

4 follow-up time from NHSII and even short follow-up

5 in Sist to some of the relevant time. Obviously,

6 the time will look big, but you're not following the

7 cohorts for ten years. Where is Sist follow-up for

8 ten years? Where is NHSII follow-up for ten years

9 -- I'm sorry -- about NHSII.

10 Q. NHSI did have a follow-up of well over ten

11 years.

12 A. Yeah. I'm talking about NHSII. You're

13 adding time just to inflate the denominator, but you

14 don't have what they're asking for. And then it's

15 also a question of "Where did they come up with this

16 1.2?" That's just their, you know -- I mean, I cite

17 it. But they said "Well, say we want to estimate

18 this 1.2 risk." That's, you know -- somebody might

19 want to do 1.1. Others we've seen in case control,

20 they may be 1.3. So you may need, you know,

21 different numbers. So that's one.

22 The main thing is etiologically relevant

23 exposure. It's not just ten years of follow-up.

24 What kind of follow-up are you getting? If you add

25 NHSII follow-up, it's very early follow-up. So you

Page 182 Page 184 1 mish and mash early with late. 1 meta-analyses in your report; right? Q. Again, you mentioned earlier today you A. Most of them were already discussed in the 3 don't believe the NHSII results influenced the 3 prior deposition. I mean, I'm happy to discuss 4 this --4 pooled --5 A. It is a minor influence. Q. Not all of them, but yes. Q. Minor influence. A. We can talk about it. I have to go to my 6 6 7 A. Yeah. Yeah. 7 report. 8 Q. Okay. 8 MR. MARTIN: Can we go off the record A. But, you know, in the pooled hazard ratio, 9 very briefly? 10 because the point estimates are .81, you know, it 10 (A break was taken) 11 appears that there's a decrease. But most of it is 11 MR. MARTIN: Back on the record. 12 because the follow-up time is limited. 12 Q. We were discussing before the break your Q. You would agree that the average follow-up 13 comment that none of the individual cohorts had more 14 time across the cohorts pooled in O'Brien is greater 14 than -- had anywhere near 200,000 women; right? 15 than ten years. 15 A. That's correct. A. Yeah. But, you know, the question is "What 16 Q. Okay. Let's look at limited statistical 17 -- is that follow-up time etiologically relevant?" 17 power in -- towards the bottom of page 11 of your 18 Yes, based on the Narod article, they said if you 19 want to detect 1.2, you would need 200,000 women. 19 MS. PARFITT: I'm sorry, Zack. What 20 But did they follow these 200,000 women? And when 20 page? 21 21 they did the etiologically relevant -- that is the MR. MARTIN: 11. 22 patent tract -- they saw it. 22 MS. PARFITT: Thank you. 23 Q. "The number of cases of ovarian cancer See, the Narod article doesn't talk about 24 any confounder adjustment. So you have to follow up 24 studies in 24 case control studies, N equals 25 the susceptible group for that period of time to see 25 13.421." So in this case, with the case control Page 183 1 the risk. 1 studies, you are pooling or adding together the Q. So let's go back to your statement that the 2 different studies to come up with the sample size; 3 -- none of the individual cohorts evaluated 200,000 4 women. Had you looked at -- did you look at A. No. So, again, I'm not making comment 5 individual cohorts because you do not believe that 5 about sample size. I'm just saying there is a --6 the various cohorts can be productively pooled? 6 the number of cases in the case control studies 7 significantly exceeds the cases even with the A. No. They can be pooled, and they did it. 8 But you have to look at the limitations of such 8 largest pooled analysis. That's all. 9 pooling. It's not -- power calculation for case 10 Q. Okay. 10 control study is not the same as -- so what Narod A. They were pooled. I mean, there had been 11 points out is, in the context of cohort study, you 12 pooled case control studies as well. But when you 12 start out with exposure and measure outcomes. When 13 harmonize data as -- we understood how they had to 13 you do a power calculation -- in fact, that is the 14 make some choices about exposure and duration and 14 efficiency of case control studies -- is their power 15 frequency, the similar thing about follow-up. They 15 to detect associations between exposure such as talc 16 pooled it together. But they pooled etiologically 16 and -- so the power calculation -- I'm not doing a 17 irrelevant -- I use that term -- versus -- with 17 power calculation. I'm just pointing out a 18 relevant, you know, that ten-year time they're 18 statement of fact, that the number of cases is more. 19 talking about. And that inflates denominator. 19 Q. My initial question was just whether the N Q. Well, I'm glad you mentioned case control 20 equals 13,421 is pooling all 24 case control studies 21 studies because there are meta-analyses of case 21 that you discuss there. 22 control studies that also combine different 22 A. Yeah. I mean, I have to look at which 23 samples --23 reference that is. Penninkilampi --24 A. Yeah. 24 Q. Penninkilampi? 25 Q. -- correct? And you cite some of those 25 A. -- total, name of case, number. That's

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1 all.

- Q. Does power increase linearly with sample3 size?
- 4 A. Power is not only a function of, you know,
- 5 sample size. It's a function of, A, which group are
- 6 you talking about. Have you -- are you going to
- 7 adjust for confounders? Are there strata that
- 8 you're -- are etiologically relevant? So it's not
- 9 just about sample size. Power is relevant to other
- 10 kind of questions you set up.
- 11 Q. To the extent sample size influences power,
- 12 is that relationship linear?
- 13 A. When you say "linear," what do you mean?
- 14 Can you give an example?
- 15 Q. Sure. Is a six-times-larger sample six
- 16 times more powerful than a sample one sixth of the
- 17 size?
- 18 A. Six times more -- no. But case control
- 19 studies are more powerful in terms of power in
- 20 detecting association. I mean, that is irrespective
- 21 of -- this number could have been only 3,000. It
- 22 didn't have to be 13,000. This is just an
- 23 observation of numbers.
- 24 This is not about -- but the comment about
- 25 power of case control studies is in the first report

- 1 A. Yeah.
- Q. Can we look at page 253?
  - MS. PARFITT: If I can have a copy,
- 4 please.

3

6

- 5 THE WITNESS: Sorry.
  - MS. PARFITT: No. It's okay.
- 7 A. 253.
- 8 Q. Can we look at the first paragraph of the
- 9 second column beginning -- well, first of all, Berge
- 10 2018 was a meta-analysis of the case controlled and
- 11 cohort studies that were existing at that time; is
- 12 that right?
- 13 A. It's 2016; right?
- 14 Q. 2018.
- MS. PARFITT: The bottom, 2018.
- 16 A. Copyright but accepted 2016 was -- I'm just
- 17 trying to -- I don't have a problem --
- 18 Q. It's copyright 2018.
- 19 A. Okay. That's fine.
- 20 Q. But it was a -- but you are correct. It
- 21 looks like it was accepted in 2016.
- 22 A. Yeah.
- Q. So my question is this is a meta-analysis
- 24 of the case control and cohort studies probably that
- 25 were, as you said, existing as of 2016. Right?

- 1 when I talk about study designs. Case control
- 2 studies are more powered to detect the associations.
- 3 Q. Is a -- even holding constant the number of
- 4 cases, in other words, is a case control study that 5 has 2.000 cases of ovarian cancer more powerful than
- 6 a cohort study with 2,000 cases of ovarian cancer?
- 7 A. Again, you have to do confounding, bias,
- 8 other things. But yes. I mean, you could -- in
- 9 general, case control studies are more adequately
- 10 powered, you know, holding other things constant.
- 11 Q. And the increased power in case control
- 11 Q. This the increased power in case contro
- 12 studies is not only a function of the increased
- 13 number of cases they generally have.
- 14 A. No. Because they -- partly is a function
- 15 of the fact that they already start out with cases.
- 16 So they can, you know, recall exposure.
- 17 Q. Do you recall citing a study by Berge, 2018
- 18 in your initial report?
- 19 A. Yes.
- MR. MARTIN: Can that be marked as
- 21 Exhibit 21?
- 22 (2018 article by Wera Berge, et al.,
- 23 Exhibit 21, marked)
- Q. You're familiar with the Berge article,
- 25 2018?

- 1 A. Sure.
- Q. Okay. And looking at that paragraph I was
- 3 pointing to earlier, beginning with "It should be
- 4 noted," "It should be noted that the cohort studies
- 5 included in the meta-analysis comprised a total of
- 6 429 cases of ovarian" -- "cases of ovarian cases,"
- 7 which I assume is a typo.
- 8 A. I'm sorry. Where are you?
- 9 Q. Sure. Middle of the first paragraph?
- 10 A. Got it.
- 11 Q. "It should be noted that the cohort studies
- 12 included in the meta-analysis comprised a total of
- 13 429 cases of ovarian cancer (verbatim) exposed to
- 14 genital talc and 943 unexposed cases. The
- 15 statistical power of the meta-analysis of this" --
- 16 "of these cohort studies to detect a RR of 1.25,
- 17 similar to the result of the meta-analysis of the
- 18 case controlled studies, was 0.99. Thus, low power
- 19 of cohort studies cannot be invoked as explanation
- 20 of the heterogeneity of the results." Do you
- 21 disagree with that statement by --
- 22 A. Let me read it first a little bit. I
- 23 completely disagree with them. I think they are
- 24 conflating two different issues. They are saying
- 25 that there are 429 cases in the -- it should be

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- 1 noted that cohort studies included in the
- 2 meta-analysis comprise a total of 400 cases and 940
- 3 unexposed cases. What is unexposed cases? Is it
- 4 controls?
- 5 Q. I believe they mean cases of ovarian cancer
- 6 who are not -- who are not exposed to talcum powder.
- A. The statistical -- I'm just trying to
- 8 unpack what are they trying to say. The statistical
- 9 power of the meta-analysis to detect an RR similar
- 10 to the results of the meta-analysis -- okay. So
- 11 they are saying "We want to do a power calculation
- 12 for 1.25." Was .99? I don't know how they come up
- 13 with that number.
- 14 Q. But you have not done a formal power
- 15 calculation of this type of your own; right?
- 16 MS. PARFITT: Objection. Form.
- 17 A. I don't know -- I have to go back and look
- 18 at my previous report if I -- I know I talked about
- 19 power. I don't know if I did a power calculation.
- 20 Q. You did not do one in your 2023 report.
- 21 A. No. And the reason is post hoc power
- 22 calculations are, in fact, you know, frowned upon
- 23 and not statistically appropriate. Even in this
- 24 case, once they have completed the analysis, trying
- 25 to invoke power as an explanation for the
- Page 191
- 1 calculation, as in, like, .99 -- "Oh, they have a
- 2 lot of power." No. It's a design issue. You begin
- 3 -- you start to think about power before you design
- 4 the study.
- 5 Q. So is your testimony that the statistical
- 6 analysis done in this Berge study is inappropriate?
- 7 MS. PARFITT: Objection.
- 8 A. It is flawed. It's methodologically flawed
- 9 because this power calculation is post hoc.
- 10 Q. Let's look at Exhibit 22, Taher, et al.,
- 11 2019.
- 12 (2019 article by Mohamed Kadry Taher, et
- 13 al., Exhibit 22, marked)
- 14 Q. So you talk about Berge or -- excuse me.
- You talk about Taher on page 5 of your 2023
- 16 report --
- 17 A. Sure.
- 18 Q. -- Paragraph 2.
- 19 A. Let me get there. Yeah.
- 20 Q. You talk about the odds ratio and
- 21 confidence interval reported in this study. Let's
- 22 go and look at Table 2 of the Taher study, which is
- 23 all of page 93.
- Let's go to Bullet 4 in that table -- which
- 25 candidly is not the most clear presentation of data

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  1 I've ever seen -- to tumor histology. Do you see
  - 2 where I am?
  - 3 A. Yes. Okay.
  - 4 Q. Okay.
  - 5 MS. PARFITT: Are you there?
    - THE WITNESS: Yes. I can see it.
  - 7 Q. What's the effect estimate for mucinous
  - 8 cancer?

6

- 9 A. 05 with wide confidence intervals, .85 to
- 10 1.29. Is that -- I mean, I'm looking at the rows
- 11 across.
- 12 Q. That's correct. That's what I see as well.
- 13 A. It's not very easy to.
- 14 Q. That's what I see as well. Do you consider
- 15 that to be data that supports an association between
- 16 mucinous cancer and talcum powder exposure?
- 17 MS. PARFITT: Objection.
- 18 A. You know, I've evaluated -- again, sort of
- 19 going back to my assessment of epithelial ovarian
- 20 cancer. I mean, here, there are data suggest --
- 21 pointing out to increase endometrial. The numbers
- 22 when you go to mucinous are so low that it is not --
- 23 you know, that the fact that they see only 1.05 is
- 24 reasonable. But my assessment is on epithelial
- 25 ovarian cancer, of which mucinous is a subtype.
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  - Q. So my next -- I'd like you to look at
- 2 clear-cell. You see the effect estimate there is
- 3 0.63 with a very wide confidence interval?
- 4 A. Yeah. But other studies have reported
- 5 elsewhere. You know, Terry's pooled analysis, you
- 6 know, provided an increased risk of -- yes. In this
- 7 analysis, they don't report it. But I'm not going
- 8 to disaggregate -- I mean, it is relevant that these
- 9 are different histologic subtypes of cancer. But my
- 10 causality assessment applies to epithelial ovarian
- 11 cancer.
- 12 Q. Did you say -- did you mention an article
- 13 that you think shows an association between clear-
- 14 cell cancer and talc specifically?
- 15 A. Terry.
- 16 Q. Terry.
- 17 A. Yeah.
- 18 Q. That's Terry 2013?
- 19 A. Yes. We can look it up.
- 20 MS. PARFITT: No. We talked quite a bit
- 21 about Terry in the last deposition.
- Q. But just to, again, be clear, your analysis
- 23 is not broken down by histological subtype.
- 24 A. No. I'm just focusing on -- I'm pointing
- 25 out where data suggests this or that.

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Page 194 Q. Okay. Let's look at the "duration of use" 2 bullet, which is about halfway up the page in the

3 same --

- 4 A. Table?
- Q. -- table. 5
- A. They have to do better tables.
- 7 Q. Some lines would be helpful, really.
- 8 A. Okay. Got it.
- Q. Okay. Do you see that 20-plus years
- 10 produces the lowest point estimate and the only one
- 11 that's not statistically significant?
- 12 A. Yeah. But that's only one -- that's one
- 13 aspect of exposure. We've discussed, I think, in
- 14 the past report and -- that exposure is not just
- 15 duration. It's intensity. It's frequency,
- 16 application. And then if you extend to the Table 4,
- 17 it provides several studies that provide --
- 18 Table 3 -- sorry -- several studies that provide,
- 19 you know, the right metric for those estimations,
- 20 not all of them, you know. There are some studies
- 21 that do not.
- 22 But there are some studies that provide,
- 23 based on the appropriate metric, such as Cramer,
- 24 Harlow, Mills, Whitmore, Wu, and Schildkraut. I
- 25 don't know how you spell that. It depends on the
  - Page 195
- 1 metric and the specific study.
- Q. Would you agree that, to the extent studies
- 3 are able to estimate total lifetime applications,
- 4 some of them demonstrate a dose response and some of
- 5 them do not?
- MS. PARFITT: Objection. Form.
- 7 A. I mean, I talked about in general, you
- 8 know, the whole body of evidence in dose response.
- 9 Some studies provide evidence of dose response.
- 10 And, you know, I have to go back and look at the
- 11 references in my previous report because that
- 12 clearly outlines which is frequency, which is
- 13 duration, which is frequency and duration. And, you
- 14 know, you can bring it up, and we can go through
- 15 study by study.
- 16 Taher, what he does is he -- I presume --
- 17 is he identifies five studies in the positive trend
- 18 with frequency. Two studies suggested there might
- 19 be an exposure response. Then there are other
- 20 studies that did not.
- 21 So there's, you know -- that's why in my
- 22 causality assessment, you know, I provided that
- 23 context in assessing dose response.
- Q. Let's look at -- let's go one page back or
- 25 -- two pages back. I apologize. Three pages back.

- A. Table 2 again? 1
  - Q. No. I'm sorry. All the way back to
- 3 page 91, Section 3.1. First sentence of the final
- 4 paragraph, "63 percent -- N equals 19 -- of the
- 5 studies concluded the presence of a positive
- 6 association between perineal" --
- 7 MS. PARFITT: Do you see that?
- 8 THE WITNESS: Where is that?
- 9 MS. PARFITT: Page 91. He's on the
- 10 wrong page.
- 11 THE WITNESS: I'm on the wrong page.
- 12 MS. PARFITT: 91. Here at the bottom.
- 13 63.
- 14 THE WITNESS: Got it.
- 15 Q. Do you see "63 percent -- N equals 19 -- of
- 16 the studies concluded the presence of a positive
- 17 association between perineal talc -- exposure to
- 18 talc -- perineal exposure to talc powder and ovarian
- 19 cancer risk. 10 studies concluded the absence of an
- 20 association. Only one study could not reach a clear
- 21 conclusion"? Do you believe that shows consistent
- 22 literature?
- 23 A. Yeah. To go to consistency, it's not just
- 24 about "This study showed this," you know, showed a
- 25 positive -- I mean, you'd have to actually read my
- 1 section on consistency.
- 2 Consistency is about, you know -- there's
- 3 going to be different point estimates because
- 4 different study designs and populations and whether
- 5 it's case controlled or cohort, even within case
- 6 controlled. But are there confidence intervals
- 7 overlap? When they pool these estimates in the same
- 8 Table 2, they don't find evidence of statistical
- 9 heterogeneity, if you look at the I squares for case
- 10 control or cohort.
- 11 So consistency involves examining study
- 12 design. What does Bradford Hill talk about?
- 13 Person, place, and time. We have different persons
- 14 conducting these studies in different parts of the
- 15 world across several decades. We have no stat --
- 16 not no but very minimal statistical heterogeneity
- 17 and confidence intervals that overlap.
- 18 So yes, I agree there's consistency in this
- 19 literature. And actually, my opinion, there's
- 20 strong evidence of consistency.
- Q. So let me ask you about little evidence of
- 22 heterogeneity in the literature. Do you believe
- 23 that there's little evidence of heterogeneity
- 24 between the case control studies as a group and the
- 25 cohort studies as a group?

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- A. You misconstrued what I said. Little 1
- 2 evidence? Statistical heterogeneity in the
- 3 meta-analysis and then a specific measure of that
- 4 known as I square.
- And so if you look at the I squares at --
- 6 in the hospital base or population base, usually,
- 7 you know, 50 to 70 percent are considered
- 8 significant. And all the meta-analysis never reach
- 9 that. So it's, like, 22 percent in the case
- 10 controls. And even Penninkilampi doesn't get there.
- So that's an evidence of statistical, you
- 12 know -- lack of statistical heterogenic -- that
- 13 answer to the question that there's evidence of --
- 14 there's evidence of consistency, despite differences
- 15 in point estimates, despite differences in study
- 16 design. So Penninkilampi, at least at that time,
- 17 had, you know, included those.
- Q. When you look at the 22 percent I-squared
- 19 statistic for case control studies in Table 2 --
- 20 A. Sure.
- 21 O. -- do you understand that to be a statistic
- 22 referring to comparing case control studies to each
- 23 other or case control studies to other types of
- 24 study design?
- 25 A. No. Those are pooled estimates for the

- 1 in practice.
  - 2 Then you have to look at risk of bias, look
  - 3 at how that evidence is direct to your question, how
  - 4 precise is it, is it a publication bias. And then
  - 5 you can make a conclusion.
  - Usually, GRADE is -- just by the fact that
  - 7 data here are observational, it assigns a low GRADE
  - 8 to observational studies because it doesn't matter
  - 9 in this context or any other.
  - 10 It starts out with low for observational
  - 11 studies. An observational study can only be
  - 12 up-coded for, you know, directness or if there's a
  - 13 confounder that actually bias them towards an
  - 14 amount.
  - 15 So yes, I'm very familiar with the GRADE
  - 16 framework. Actually, there's a publication on GRADE
  - 17 in my CV.
  - Q. If you look at 4.4, Section 4.4, which is 18
  - 19 page 98 of this.
  - 20 A. Section 4.4. Yeah.
  - 21 Q. You can see that Taher did this GRADE
  - 22 analysis here.
  - 23 A. They did.
  - 24 Q. And you agree they graded the evidence very
  - 25 low?

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- 1 case control studies.
- 2 Q. Okay.
- 3 A. Yeah.
- Q. 22 percent number there doesn't address
- 5 heterogeneity between case control and cohort
- 6 studies; right?
- A. No. And that we can look at in the
- 8 Penninkilampi meta-analysis. We should look at
- 10 Q. That was published in 2018. And I think I
- 11 will get in trouble if I look at that. So let's --
- A. No. But there are other -- when you pool
- 13 them, you still don't reach that level of concern
- 14 about statistical heterogeneity.
- Q. Let's look -- well, do you know what the 15
- 16 GRADE framework -- all capital letters -- is?
- 17 A. Yeah. I've written chapters for the --
- 18 Q. Can you explain it to me?
- 19 A. GRADE frameworks is not one thing, you
- 20 know. GRADE framework is a way to provide, you
- 21 know, decision-makers evidence on use of
- 22 interventions that usually apply -- you know, you
- 23 have a body of evidence. You conducted a systematic 23 effect estimate. The true effect is likely to be
- 24 review. Now you want to make guidelines or some
- 25 other decisions about using that product or using it

- A. Yes. Because they were looking at
- 2 observational data. But despite that, you know,
- 3 they rated the studies in that Table 2 we were
- 4 looking at as, you know -- between the high and low
- 5 risk of bias as, you know -- a lot of them as low
- 6 risk of bias, which provided an increase.
- But here, they say that. But, you know,
- 8 they use the same data that -- when they go to the
- 9 full report -- which, you know, you'll probably
- 10 bring out some point in time -- they provide that
- 11 this data indicative of a causal association.
- 12 So GRADE is not necessarily a decision-
- 13 maker here. You know, GRADE is providing evidence
- 14 for decision-makers. But here, when we are making
- 15 causal determinations based on epidemiology -- which
- 16 is the only thing we have here. We're not going to
- 17 have trials.
- Q. Well, let's look at what they say "very
- 19 low" means. In Footnote A to this Table 4, they
- 20 define "very low" as --
- 21
- Q. -- "We have very little confidence in the 22
- 24 substantially different from the estimate of
- 25 effect." Do you agree with that understanding of a

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1 very low GRADE?

- 2 A. No. I don't think so. And I don't think
- 3 -- if that was what they had interpreted, then why
- 4 would -- why wouldn't they have said that "We
- 5 maintain our conclusion that talc is a possible
- 6 cause of human cancer in humans based on the
- 7 totality of evidence" and then gone on to write a
- 8 report which says that "We are confident in our
- 9 conclusion that there's a causal association" based
- 10 off the same data?
- 11 Q. So let's look at the -- what you just
- 12 mentioned, which I believe is on the next page. I'm
- 13 trying to --
- 14 A. No. It's in the same -- up line -- second
- 15 paragraph.
- 16 Q. No. I'm looking at the following paragraph
- 17 at the beginning of page 99 halfway through. I
- 18 thought that's what you were --
- 19 A. No, I'm not.
- 20 Q. -- looking at as well because it says
- 21 "Despite the very low certainty assigned by the
- 22 GRADE evaluation, which heavily favors RCTs" --
- 23 which you mentioned earlier, randomized control
- 24 trials --
- 25 A. Yeah.

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- Q. -- "we maintain our conclusion that talc is
- 2 a possible cause of human cancer in humans, based on
- 3 a totality of the evidence." That's what I thought
- 4 you were referring to earlier.
- 5 A. I was. But then I also -- they use largely
- 6 the same data. They update it in the Health Canada
- 7 report and go further and say that "We are confident
- 8 that there is indicative of a causal association."
- 9 So I have done lots of grading myself. And I'm just
- 10 trying to explain how it works.
- 11 You know, most of the observational
- 12 literature we do, we start out with low. And you
- 13 are sort of stuck with the framework. It was really
- 14 designed to assess interventions, like drug
- 15 pharmaceutical trials and randomized control trials.
- 16 It wasn't designed for this particular --
- 17 Q. So I just want to focus on the "talc is a
- 18 possible cause of human cancer" that you brought up
- 19 here in this passage. Then we can talk about Health 20 Canada.
- Is it your opinion that talc is a possible
- 22 cause of human cancer, or is it your opinion that
- 23 talc is a cause of human cancer?
- 24 A. No. I'm just quoting the statement they
- 25 state here, despite all the limitations. I believe

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- 1 -- I'm of the opinion that talc is, you know, causal
- 2 and relates to the -- is a causal risk factor in the
- 3 development of ovarian cancer.
- 4 Q. Would you agree with me that that's a step
- 5 further than the statement here in this paragraph?
- 6 A. Yes. Which is the same statement they made 7 in Health Canada. Yeah.
- 8 Q. You would agree with me, also, that it's --
- 9 that what -- the statement in this paragraph is
- 10 consistent with IARC's classification of talc.
- 11 A. Yeah. But that was in 2006. There was
- 12 hardly any -- there were some studies at that time.
- 13 But they didn't have all the data that they had or I
- 14 have now.
- 15 Q. I'm just trying to understand the meaning
- 16 of "possible" here.
- 17 A. Yeah. But remember, you know -- so let's
- 18 unpack that a little bit. When you say "possible"
- 19 and "probable" in that context -- IARC context --
- 20 it's not the same as here, Taher. "Possible" and
- 21 "probable" in the IARC context could mean Group 2B
- 22 to Group 2A. We're not talking about that here.
- I mean, they don't even explicate are you
- 24 talking about mechanistic data, are you talking
- 25 about animal data, have you ruled out bias,

- 1 confounding. So you can't just use terms "possible"
- 2 and "probable" in the same sentence and equate this 3 to IARC.
- 4 Q. Okay.
- 5 A. IARC is different. And I've done the work
- 6 for IARC too.
- 7 Q. You mentioned Health Canada, which includes
- 8 some of the same --
- 9 A. Yeah.
- 10 Q. -- scientists as this and, you suggested,
- 11 reached a stronger conclusion about the
- 12 carcinogenicity of talc than this article did?
- MS. PARFITT: Objection. Misstates the
- 14 testimony and the evidence.
- 15 A. I just -- my -- I'm just going to say what
- 16 conclusion they read. You interpret it as stronger.
- 17 They interpret it as confidently evidence of a
- 18 causal -- indicative of a causal association.
- 19 That's all I mean. It is strong.
- 20 Q. So we may get to the Health Canada report
- 21 later this afternoon, but I just want to ask you
- 22 now. Do you know the standard of review which
- 23 Health Canada uses under Canadian law?
- 24 A. I mean --
- MS. PARFITT: Objection.

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Page 206 A. -- they are a regulatory body. I mean, I

- 2 don't know all the specifics of -- yeah. But, I
- 3 mean, they have a 350-page supplement. I was trying
- 4 to review it. They are very detailed, very
- 5 meticulous. I am very impressed with their work.
- Q. Do you understand the standard applied in
- 7 regulatory law to be the same as the standard
- 8 applied in tort law?
- MS. PARFITT: Objection. Form.
- 10 A. I mean --
- 11 MS. PARFITT: He's not a lawyer.
- 12 O. If the answer is you don't know, that's
- 13 fine.
- 14 A. I'm not a lawyer. I mean, I provide an
- 15 epidemiologic assessment on causation. I'm familiar
- 16 with IARC. I'm familiar with GRADE. You can ask me
- 17 all questions you want about how IARC comes to
- 18 probable and possible or, you know, sufficient
- 19 evidence.
- 20 The only thing I review is the details and
- 21 the methods and how did they come to that
- 22 conclusion. And they evaluate O'Brien. In fact,
- 23 several studies have been published after Health
- 24 Canada published their report.
- 25 Q. Are you familiar with Davis 2021?

1 plaintiffs' expert in this litigation?

- A. Yeah. I skimmed through her deposition.
- 3 Q. We've asked this a couple of times. Did
- 4 that affect the way you evaluated the Davis paper in
- 5 your expert report?
- MS. PARFITT: Objection. Asked and 6 7 answered.
- A. You know, it's the same. I looked at the
- 9 methodology. I looked at disclosures. But, you
- 10 know, this is a, you know, consortium of
- 11 researchers, ovarian cancer -- they've published
- 12 many studies, not only these studies -- well-reputed
- 13 scientists, not just Dr. Moorman but others as well.
- 14 So, you know, it's not just her study.
- 15 Right? It's all these people. Schildkraut has
- 16 conducted many studies. So I have to look at the
- 17 methodology.
- Q. You understand one of the purposes of this
- 19 study or the primary purpose of this study was to
- 20 examine talc use specifically in the African
- 21 American population; correct?
- 22 A. Yeah.
- 23 Q. Okay. And would you agree with me that
- 24 some studies show a greater use of talcum powder
- 25 among African American women than white women?

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- 1 A. Yes.
- 2 MR. MARTIN: Okay. Let's mark this as
- 3 the next exhibit.
- (2021 article by Colette P. Davis, et 4
- 5 al., Exhibit 23, marked)
- Q. You talk about this in pages 8 and 9 of
- 7 your expert report, I believe.
- A. Give me one second. Let me give it to
- 9 them. You said which page?
- 10 Q. I haven't said a page yet.
- A. Okay. You said some page of your report. 11 than white cases and controls." 11
- 12 Q. Yes. I'm sorry. It's -- I was just saying
- 13 you talk about Davis on pages 8 and 9 of your
- 14 report.
- 15 A. Okay. That's all.
- 16 Q. I believe.
- 17 MS. PARFITT: Do you have the Davis? 17
- 18 May I have one copy of that?
- 20 of authors on page 1660 of the Davis article?
- 21 A. Yeah.
- 22 Q. It's the list of authors.
- 23 A. Yeah. I didn't go through all the list,
- 24 but I see it now. Yes.
- 25 Q. Are you aware that Dr. Moorman is a

MS. PARFITT: Objection. Form.

- A. That is correct.
- Q. Can we turn to page 1663, first paragraph,
- 4 the sentence that begins "Across most study sites"?
- 5 A. 66?

1

- 6 Q. 63.
- 7 A. I'm sorry.
- Q. "Across most study sites, AA cases and
- 9 controls had a higher prevalence of ever use,
- 10 frequent use, and long-term use of genital powder
- 12 So would you agree with me that African
- 13 American women not only used talcum powder at a
- 14 higher rate but use it more frequently on average
- 15 and for longer term on average?
- A. Based on this study, yes.
- Q. Okay. Let's turn to Table 3. It's 1665.
- 18 It's the top of 1665. Okay. And the all-case point
- Q. So you see Dr. Moorman's name in the list 19 estimate for African American women is 1.22 with a
  - 20 confidence interval that crosses 1. Do you see
  - 21 that?
  - 22 A. Yes.
  - 23 Q. You see that, among white women, it's 1.36,
  - 24 a higher point estimate and statistically
  - 25 significant confidence interval? Do you see that?

53 (Pages 206 - 209)

A. Give me -- yes.

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- 2 Q. Okay. Do you have a theory for why the
- 3 risk would be lower among African American users,
- 4 despite using the product more frequently and for a
- 5 longer period of time?

1

- 6 A. I don't think it's lower. It's -- those
- 7 two estimates are -- the authors conclude that they
- 8 are no different. The tests of interaction were not
- 9 significant. The confidence intervals are not --
- 10 you know, overlapping. So I don't think they are
- 11 lower. I mean, those are -- the point estimates
- 12 appear to be lower, but.
- 13 Q. You mentioned the confidence intervals are
- 14 overlapping, despite the fact that the point
- 15 estimates are different.
- 16 A. Are lower.
- 17 Q. The point estimate for African American
- 18 women is lower. When we were talking about the top-
- 19 line results in O'Brien, you told me that it didn't
- 20 matter that the confidence interval overlapped 1.0.
- 21 So I'm just trying to understand --
- 22 A. Sure.
- 23 Q. -- when you look at point estimates and
- 24 when you look at confidence intervals.
- 25 A. I look at both. There's no, like,

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- 1 selective looking. It's, like, when you're trying
- 2 to compare the confidence intervals to examine
- 3 consistency. So it's not like you're making a
- 4 statement about strength. It's more about "Are the
- 5 two findings consistent?" And we should say what
- 6 they stated. Give me a second, and let me see what
- 7 they state about the results.
- 8 In this study, ever use was associated with
- 9 higher odds in both AA and white women. And the
- 10 population was similar in those groups, was --
- 11 that's it. So there's no difference between the two
- 12 groups. No evidence of heterogeneity by race was
- 13 observed.
- 14 Q. What I'm struggling with is, if the white
- 15 results and the African American results are
- 16 consistent because their confidence intervals
- 17 overlap, why wouldn't that mean that the O'Brien
- 18 results are consistent with 1.0 because the
- 19 confidence interval overlaps that? What's the
- 20 difference?
- 21 A. With whom?
- 22 MS. PARFITT: Objection. Form.
- 23 A. So the question is these -- I'm comparing
- 24 two different studies. You know, not even -- two
- 25 different analysis. And here, you have a test of

1 interaction that is not significant.

- 2 So you have two where they state that both
- 3 are elevated and test of interaction was not
- 4 significant. And there's, you know, there's a lot
- 5 of overlap. They're the ones --
- 6 Q. Can you point me to the test of
- 7 interaction, please? I'm not seeing it.
- 8 A. Yeah. So you go to the second paragraph of
- 9 the results -- okay -- "Ever use of genital powder"
- 10 -- in page 1663.
- 11 Q. Yes.
- 12 A. Second paragraph, ever use was associated
- 13 with 32 percent higher risk. Then they provide a
- 14 confidence interval. When stratified by race among
- 15 -- the 36 percent among white women pooled also
- 16 shows significant, and nonsignificant higher risk
- 17 among African American women. So, you know, again,
- 18 36, 22 (verbatim) but no evidence of heterogenic.
- 19 So that is a test of interaction. That's what I'm
- 20 basing -- it's not just confidence intervals.
- 21 There's a test of interaction.
- 22 Q. Is it your position that, when a point
- 23 estimate is elevated and P equals 0.33, that does
- 24 not show a difference?
- 25 A. Where is P 0.33?

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- 1 MS. PARFITT: Objection. Form.
  - 2 Q. "No evidence of heterogeneity by race
  - 3 observed," parentheses, "P equals 0.33."
- 4 A. Yeah. So that is their conclusion. It's
- 5 not just my conclusion. There's no evidence of --
- 6 that's a test of interaction, P-value. That's not a
- 7 test -- that's not a stratum-specific P-value.
- 8 That's, when they compare the two groups, what is
- 9 the P-value? It's a stratum, you know. It's for
- 10 the test.
- 11 Q. Understood. Understood.
- 12 A. And I do agree with the authors that
- 13 there's no evidence of heterogeneity by race.
- 14 Q. You pushed back strongly this morning on
- 15 drawing a firm line at P equals 0.05; correct?
- 16 A. Sure
- 17 Q. You do in your report as well.
- 18 MS. PARFITT: Object to the form. You
- 19 may continue.
- Q. At what P-value do you draw the line to say
- 21 that two values are different from one another?
- A. So I wouldn't draw the line. I'm just, you
- 23 know, interpreting what they said in terms of tests
- 24 of interaction, which are notoriously underpowered. 25 So even though they're underpowered, there are no

54 (Pages 210 - 213)

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1 difference.

- I don't have a P-value which I can say
- 3 that, you know -- and sometimes authors, you know --
- 4 it depends on the context. You know, is a P of .051
- 5 not significant or P of .049 not -- P-value is just
- 6 a statement that the data you have, you know, is --
- 7 the probability of having a data as a more extreme
- 8 under the hypothesis being two. It has no direct
- 9 relevance to clinical significance other than
- 10 interpretation. You know, it's a statement of the
- 11 null hypothesis.
- 12 Q. Do you have to draw the line somewhere?
- 13 A. Yeah. I mean, you have to draw the line in
- 14 the context of what other data you have.
- 15 Q. Can we turn to 1667? Last sentence of the
- 16 article, "Furthermore, there was not a dose-response
- 17 relationship between frequency or duration of
- 18 genital powder use in ovarian cancer risk or any
- 19 significant differences in association by
- 20 histotype." Did you consider this in your dose
- 21 response section of your report?
- 22 A. Yeah. I mean, it's in the -- noted. I'll
- 23 read it for you. There was no differences. I have
- 24 the exact statement: "By frequency of" -- page 9 --
- 25 "By frequency of genital powders" -- if you go to
  - Page 215
  - 1 page 9 of my report, it talks about "There was no
- 2 difference in the association by frequency of
- 3 genital powder use, although both reported an
- 4 increased risk."
- 5 Q. My question was about the section of your
- 6 report where you discuss -- you know what? Strike
- 7 that question.
- 8 Can we move back to the previous column on
- 9 the same page?
- 10 A. I didn't finish answering the question.
- 11 You asked me a question.
- 12 Q. I'm sorry. I thought you were done.
- 13 A. No. You asked me a question, "Did you
- 14 discuss the data of no dose response relationship in
- 15 your report?" And I want to point out page 9 of my
- 16 report, second-to-last paragraph explicitly
- 17 discusses that.
- 18 Q. Okay. Thank you. If you move to the
- 19 previous column on page 1667 of Davis. Right.
- 20 First full paragraph, second paragraph -- and this
- 21 is, again, talking about dose response. Do you see
- 21 is, again, taiking about dose response. Do you see
- 22 where it says "We observed"?
- 23 A. Sorry. Second column?
- 24 Q. First column, second paragraph, "We
- 25 observed."

- A. Yeah.
- Q. "We observed no clear dose-response trends.
- 3 In contrast, AACES" --
  - MS. PARFITT: No. No. Read the whole
- 5 sentence. Says "We observed no clear dose-response
- 6 trends for frequency or" --
  - Q. "Frequency or duration of genital powder
- 8 use and ovarian cancer risk among AA women or white
- 9 women. In contrast, AACES reported significant
- 10 trends for both frequency -- less than 30 times per
- 11 month," comma, "daily use, and duration, less than
- 12 20 years, greater than or equal to 20 years of
- 13 genital powder use respectively.
- "While different than AACES's, our results"
- 15 -- meaning the no-dose-response results -- "are
- 16 consistent with most prior studies that report no
- 17 significant dose response association between
- 18 genital powder use and ovarian cancer risk." Do you
- 19 agree with Davis's summary of, quote, "most prior
- 20 studies"?
- 21 A. No. And you can go back to my previous
- 22 testimony, cites the studies that have, cites the
- 23 studies that don't. And when they say "most," you
- 24 can look at the references. They have, you know, 21
- 25 to 25. So that's five, you know -- five -- 21 --
  - Page 217
- 1 that's six studies.
- We already saw, in Taher, he presented data
- 3 from seven studies. You know, five are consistent
- 4 and then two suggest. So I don't know what
- 5 interpretation they provide. But in their study,
- 6 they did not find. And that, I have included in my
- 7 report.
- 8 Q. Yeah.
- 9 A. And most importantly, they did not
- 10 ascertain the duration and frequency -- the lifetime
- 11 applications, which is appropriate way to address
- 12 dose.
- 13 Q. You would agree that some of the studies on
- 14 which you relied for showing of dose response also
- 15 do not ascertain --
- 16 A. Yes.
- 17 Q. -- the exact lifetime use.
- 18 A. Yes.
- 19 Q. Okay. Can we flip back to page 1663?
- 20 A. Yes.
- 21 Q. Second paragraph, "When restricted to" --
- 22 in the middle of the paragraph. Do you see that?
- A. Give me a second. First column or second?
- 24 Q. First column. Thank you.
- MR. TISI: Where are you?

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MR. MARTIN: Page 1663, second

2 paragraph.

1

- 3 A. Yes.
- 4 Q. "When restricted to women with patent
- 5 reproductive tracts, the OR among all women was
- 6 1.27, 1.09 to 1.48. Among women without patent
- 7 reproductive tracts, the corresponding OR was 1.42,
- 8 1.17 to 1.72." Did you consider this study in your
- 9 evaluation of O'Brien's patent reproductive tract 10 data?
- 11 A. When you say "this study" and "that data,"
- 12 I mean, you look at the P for heterogeneity. It's,
- 13 again, nonsignificant. So it is -- I'm going to go
- 14 to my section and see what I commented or not.
- 15 Yeah. I did not comment on that.
- But when they did the stratum-specific
- 17 analysis, while they report a higher risk with --
- 18 without tracts, again, they are not different. And
- 19 that actually goes to my counterargument for
- 20 Gossett, that it is entirely plausible that women
- 21 without patent tracts have risks similar to women
- 22 with patent tracts. That's what you're seeing here.
- 23 So yes, if we consider this, then --
- 24 although these are not different. I don't think
- 25 they are different estimates. These are overlapping

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- 1 "Tanha, et al. conducted an umbrella review of two
- 2 systematic reviews and reported that perineal talc
- 3 use was associated with a statistically significant
- 4 increase in ovarian cancer, OR 1.279" -- excuse
- 5 me -- "297, 95 percent CI, 1.242 to 1.355, P less
- 6 than .001. Without any evidence of statistical
- 7 heterogeneity among studies, I squared equals 0
- 8 percent."
- 9 Can we look at the Tanha study we just had
- 10 marked, page 14, Table 2. Let me know when you're
- 11 there.
- 12 So perineal talc in Table 2, it says "OR
- 13 1.297." And for that row, there's an I squared of
- 14 0.0. Says there's two studies. Then it says "RR
- 15 1.250, I squared 38.11," two studies. So would you
- 16 agree with me there's four total talc studies
- 17 included in the Tanha article?
- 18 A. Not really. I mean, I don't understand
- 19 when you say "RR."
- Q. I count four?
- A. Which are the four?
- Q. No. 6 -- turning back to Table 1, page 3.
- 23 A. Okay.
- Q. No. 6 is Penninkilampi. Do you see that?
- 25 A. Table 1 -- okay. Table 1. Yeah.

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1 estimates. Test of interactions are not

- 2 significant, but interpretation could be that women
- 3 with patent and nonpatent have similar estimates.
- 4 Q. Let's look at Perez 2018.
- 5 THE WITNESS: If you have several
- 6 questions, I'll take a break.
- 7 MR. MARTIN: Yes. We can take a break
- 8 now. Off the record.
- 9 (A break was taken)
- MR. MARTIN: Back on the record. Before
- 11 we went off the record, I shared with you a Perez
- 12 study but --
- 13 THE WITNESS: I don't have it.
- MR. MARTIN: -- we're not going to do
- 15 it. Instead, we're going to move on to Tanha 2021,
- 16 which I'd like to have marked in place of the
- 17 previous exhibit.
- 18 (2021 article by Kiarash Tanha, et al.,
- 19 Exhibit 24, marked)
- Q. This is cited in page 6 and 7 of your
- 21 supplemental expert report.
- 22 A. Yeah. It's a brief reference to that.
- 23 Q. Yeah. And what you say in your
- 24 supplemental -- I'm sorry. I really shouldn't --
- 25 it's page 6 of your expert report, Paragraph 3.

Page 221 Q. Then continuing in Table 1, No. 13, the

- 2 Berge talc use study. Do you see that?
- 3 A. Sure.

1

- 4 Q. Okay. And continuing in Table 1 -- I had
- 5 these marked in my previous copy. But on page 8,
- 6 No. 247, the Taher study of perineal talc use.
- 7 A. Yeah.
- 8 Q. Okay. And on page 5, No. 124, the
- 9 Huncharek study of cosmetic talc use.
- 10 A. Yeah.
- 11 Q. Okay. Now, turning back to -- so you'd
- 12 agree with me there are four talc studies included
- 13 in Table 1 here --
- 14 A. Table 1, yeah.
- 15 Q. -- that we just went over.
- 16 A. Four meta-analysis.
- 17 Q. Yes. If we go back to Table 2, you see two
- 18 meta-analyses that reported odds ratios and two that
- 19 reported risk ratios.
- 20 A. I don't -- so that's the question I have.
- 21 Let's figure out which -- how could these meta-
- 22 analyses report risk ratios, because these are case
- 23 control studies. Let's find out which meta-analysis 24 reported -- let's bring out the four meta-analysis
- 25 and see if they reported risk ratios.

56 (Pages 218 - 221)

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- 1 Q. This is the article you cited in your
- 2 expert report. I'm asking you if you know, based on
- 3 what you put in your expert report, what they're
- 4 citing here for the odds ratio and what they're
- 5 citing for the risk ratio.
- 6 A. Yeah. I'm aware of that. Yeah. And I
- 7 think odds ratio estimate is more appropriate when
- 8 that -- when the -- when you are pooling case
- 9 control studies and cohort studies. I mean, I don't
- 10 -- risk ratios are not appropriate -- not -- not
- 11 appropriate.
- But odds ratios are more appropriate for
- 13 case control studies. And I'm -- I would have to go
- 14 back and look at those four citations because Taher,
- 15 I know, reports on odds ratios. Penninkilampi also
- 16 reports on odds ratio. Let's see. You know, let's
- 17 bring out the other two. You said Berge. And what
- 18 else was it?
- 19 MS. PARFITT: Huncharek.
- Q. We're not going to do it for the sake of
- 21 time.
- 22 A. No. But you're right.
- 23 Q. I'm going to ask why you chose to include
- 24 the odds ratio but not the risk ratio in your expert
- 25 report.

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- 1 A. Odds ratio is much more relevant for rare
- 2 outcome. I don't see any difference between the
- 3 two. I mean, it's still, you know, 1.25, still
- 4 significant. The estimates are -- I squared is
- 5 38.1, still not a concern when you think about
- 6 statistical heterogeneity.
- 7 So it doesn't make -- you know, both are
- 8 similar. I don't know how they would even estimate
- 9 risk ratios. Maybe those studies had. But then
- 10 what is -- because lot of, you know -- most of them
- 11 are case control studies. So they are using odds
- 12 ratios.
- 13 Q. So would you agree that all four of these
- 14 studies -- Penninkilampi, Berge, Huncharek, and
- 15 Taher -- were included individually either in your
- 16 2018 or 2023 report?
- 17 A. Yes.
- 18 Q. Okay. So what, if anything, does the Tanha
- 19 study add to what those studies already provided?
- 20 A. I'm just updating my review. I'm adding,
- 21 you know, whatever other people have evaluated.
- 22 It's a different study design. It's an umbrella
- 23 review. So they have looked at other reviews.
- So, again, this is not -- this is not sort
- 25 of driving my -- as you asked, you know, that, okay,

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- 1 you know, is this -- how would we know which studies
- 2 you're basing your opinion on. This is one review.
- 3 I found it and reported it.
- 4 Q. This is not -- this Tanha article is not
- 5 just about tale; right?
- 6 A. Yeah. There's other risk factors, multiple
- 7 -- in fact, talc is a small portion.
- 8 Q. Right. So can we look at the first
- 9 paragraph of the "discussion" section on page 10?
- 10 A. Page?
- 11 Q. 10. Can you just review that paragraph?
- 12 And then we'll break it down sentence by sentence,
- 13 but can you take a moment to read all of it first.
- 14 A. Yes.
- 15 Q. So the first thing they say is -- well,
- 16 they say "As regards nutritional factors, intake of
- 17 coffee, egg, and fat can significantly enhance the
- 18 risk of OC." Do you see that?
- 19 A. Yes.
- 20 Q. And then they say "Estrogen and
- 21 progesterone therapies are also associated with
- 22 elevated risk of OC. Several diseases, as well as
- 23 some genetic polymorphisms, can significantly
- 24 increase the risk of OC. And other factors, like
- 25 obesity, overweight, smoking, and the use of

- 1 perineal talc, are also accompanied by an increased
- 2 risk of OC."
- 3 A. That is correct.
- 4 Q. Do you see that, with regards to coffee,
- 5 eggs, and fat, they say "can significantly enhance
- 6 the risk," and with regards to "obesity, overweight,
- 7 smoking, and talc," they say "are also accompanied
- 8 by an increased risk"?
- 9 MS. PARFITT: You're referring now to
- 10 the very last sentence.
- 11 MR. MARTIN: Yes. Correct.
- 12 A. Yeah. Yeah. I did not disentangled
- 13 coffee, egg, or fat and get into the minutia of, you
- 14 know, significantly or not. I mean --
- 15 Q. I'm sorry. I didn't want to cut you off.
- 16 A. Yeah. I just want to say that, you know,
- 17 this was an umbrella review relevant to the
- 18 question. Was just cited. As you can see, I
- 19 devoted two lines to it.
- Q. So you don't have an opinion on whether
- 21 there's a difference in meaning between
- 22 "significantly enhanced the risk" and "accompanied
- 23 by an increased risk."
- 24 MS. PARFITT: Objection. Form.
- 25 A. First of all, you'd have to do a causal

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- 1 analysis of coffee, ovarian cancer. I don't -- then
- 2 I would be worried about it. I'm drinking a lot of
- 3 coffee. So, I mean, that's a different, you know --
- 4 you'd have to look at it. I don't know what the
- 5 results on coffee are.
- Q. Well, that was my next question. You don't
- 7 have an opinion on eggs, coffee, or fat, do you?
- A. No. Obesity, yes, but not on eggs, coffee,
- 9 and fat.
- 10 Q. And your opinion is obesity can increase
- 11 the risk of ovarian cancer.
- 12 A. That is correct.
- 13 Q. Let's look at page 15 of this study, final
- 14 paragraph before the conclusion, so the second
- 15 column, "The ovarian carcinogenesis mechanism of
- 16 perineal talc use has remained unclear." Do you
- 17 agree with that statement?
- A. No. No.
- 19 Q. No. And why don't you agree with that
- 20 statement?
- 21 A. I mean, I think the evidence for that is
- 22 becoming much more, you know -- is as solid as
- 23 Health Canada says, and Dr. O'Brien states that in,
- 24 you know, in one of her articles, that there's, you
- 25 know -- talc is an insoluble particle and has --
  - Page 227
- 1 there's evidence of retrograde migration of talc.
- 2 And in animal studies, when applied, it can
- 3 cause epithelial reaction and trigger a chronic
- 4 inflammation which can lead to a series of mutagenic
- 5 changes and lead to carcinogenesis, which is further
- 6 aggravated if it contains asbestos.
- 7 Q. So you mentioned Health Canada. Let's take
- 8 a look at that.
- A. Which number is that?
- 10 Q. I don't think we introduced it yet. I have
- 11 a marked-up version of Health Canada. Where is
- 12 that?
- 13 MS. PARFITT: Hold on.
- (April 2021 Health Canada document, 14
- 15 Exhibit 25, marked)
- Q. I gave you a version. Are you looking for
- 17 yours with notes?
- 18 A. Yeah.
- 19 Q. So because we were talking about
- 20 plausibility and migration, I want to turn to
- 21 page 19 of the Health Canada report.
- In fact, you do, in your report, as well as
- 23 in your testimony here, rely on Health Canada for
- 24 the idea of retrograde migration; right?
- 25 A. Yes.

- Page 228 Q. Okay. Want to look at what Health Canada
  - 2 says specifically. Second to last -- well, first
  - 3 full paragraph on page 19, second-to-last sentence,
  - 4 "Studies specifically assessing potential movement
  - 5 of talc particles through the human body were not
  - 6 identified in the literature."
  - 7 A. Where is this?
  - 8 Q. Second-to-last sentence.
  - 9 A. Page 19?
  - 10 Q. Page 19, yes.
    - MS. PARFITT: Wait until you find it.
  - A. "Translocation," blah, blah, blah. Where 12
  - 13 is that?

11

- 14 Q. It's about two thirds of the way through
- 15 the first full paragraph, "Studies specifically
- 16 assessing."
- 17 A. Yeah. Yeah. Got it.
- 18 Q. "Studies specifically assessing potential
- 19 movement of talc particles through the human body
- 20 were not identified in the literature." Are you
- 21 aware of any such studies that assess the movement
- 22 of talc particles through the human body?
- A. Yes. Indirectly. I mean, and I note in 23
- 24 the, you know -- in my section on -- I mean, that --
- 25 the fact that talc has been found in ovaries, talc
- 1 has been found in lymph nodes -- I mean, when you
- 2 say "study specifically is assessing," if you're
- 3 talking about study putting a peroneal talc and
- 4 going up the, you know, vagina, cervix, uterus, no,
- 5 there is no study like that in humans.
- But there are studies which find talc in
- 7 ovarian tissues, talc in -- which provide indirect
- 8 evidence of retrograde migration of talc. And the
- 9 FDA concludes that they -- the findings that
- 10 potential particles do migrate is indisputable.
- 11 It's not just me. It's FDA, other researchers as
- 12 well, Dr. O'Brien as well.
- Q. Well, you'd agree that there are animal
- 14 studies in which talc has not migrated to the
- 15 ovaries; correct?
- A. Yeah. 16
- 17 MS. PARFITT: Objection. Form.
- 18 Q. Well, let's look specifically at paragraph
- 19 -- the following paragraph on page 19. You'd agree
- 20 that the Henderson study cited here introduced talc
- 21 into the cervical canal and did not find it in the
- 22 ovaries of rats; correct?
- 23 A. Which Henderson?
- 24 MS. PARFITT: '77, '79?
- 25 Q. Sorry. 1986. It's the one that's

Page 230 Page 232 1 discussed in Paragraph 19. 1 paper; right? A. Give me a second. This is an animal study, MS. PARFITT: Objection. 3 3 but it says talc particles were detected in ovaries A. How do I know --4 4 of all rats that received intrauterine installation MS. PARFITT: Form. 5 5 as well as rats that received intravaginal treatment A. -- if that is even correct? Like, that's 6 -- I mean, all of this was discussed in biologic 6 not my, you know, determination. I'm looking at the 7 plausibility last time. And I'm happy to discuss 7 paper disclosures. That's as much as I get into it. 8 it, but it seems like --Q. Would you agree it's not disclosed in the Q. The only thing I want to establish, that 9 paper? 10 you'd agree there are animal studies going both ways 10 MS. PARFITT: Objection. Misstates the 11 on this issue. 11 evidence in the case. 12 A. Yes. 12 A. If it occurred, it could have. I don't 13 MS. PARFITT: Objection. Asked and 13 know if it occurred; right? I have not looked at 14 her report or previous meta-analysis. I'm just 14 answered. 15 Q. Just wanted to address that very briefly. 15 looking at this published peer-reviewed manuscript, 16 We may return to Health Canada later today, but I 16 her disclosure, and her analysis. 17 just wanted to address the issue while we were on 17 Q. You agree it doesn't say it in this 18 it. Now I want to turn to Woolen 2022. 18 publication. 19 MS. PARFITT: Going to Woolen. MS. PARFITT: Objection. Asked and 20 MR. MARTIN: Can I introduce both Woolen 20 answered. 21 21 as Exhibit 26 and a supplemental table to that as A. No, it doesn't. 22 Exhibit 27? 22 MS. PARFITT: He already answered the 23 23 question. Move on. (2022 article by Sean A. Woolen, et al., 24 24 Exhibit 26, marked) THE WITNESS: Move on. 25 (Supplementary table, Exhibit 27, 25 O. You've never read Dr. Smith-Bindman's Page 231 Page 233 1 litigation reports? 1 marked) 2 A. No. Q. So you discussed Woolen in Paragraph 1 on 3 page 5, the first sentence of that page of your 3 Q. You never talked to her? 4 report, your 2023 report. "Woolen, et al. conducted 4 A. I don't know her. 5 a systematic review and meta-analysis of case Q. Okay. If this article grew out of 6 litigation work, would that affect your view of its 6 control and cohort studies and examined the 7 reliability? 7 relationship between frequent perineal exposure to 8 MS. PARFITT: Objection. 8 talcum powder, defined as multiple applications 9 greater than or equal to two times per week, and the 9 A. I've already evaluated that. And the 10 disclosure is a -- complete. We know that she's, 10 risk of ovarian cancer." 11 you know, an expert. So, as this question has been Let's look at this study. Let's look first 11 12 at the list of authors of this study. Woolen, 12 answered several times, examine the methodology, 13 Lazar, and Rebecca Smith-Bindman. Do you know that 13 acknowledge the funding sources, bias and do that 14 Dr. Smith-Bindman is an expert for plaintiffs in 14 for the same studies for, you know, Lynch and other 15 interpretations and others. 15 this litigation? 16 So it's not just you -- you know -- it's 16 A. That has been disclosed, yes. 17 okay to -- I mean, I'm not saying it's -- as long as 17 Q. Yes. And it is, in fact, listed in the 18 they're disclosed, it makes it easier for the reader 18 conflict of interest at the end. Are you aware that 19 this article grew out of a meta-analysis that she 19 to interpret the studies and understand. That's 20 all. And I'm not sure what you mean by the term 20 performed for this litigation? 21 MS. PARFITT: Objection. 21 "grew out of litigation." 22 Q. We don't have time to go through and 22 A. I have no knowledge --MS. PARFITT: Misstates the evidence. 23 compare this to Dr. Smith-Bindman's report. But 23 24 let's look at the first line of the "background" 24 A. -- of that meta-analysis.

25 section here. Let's look at the full "background"

Q. You agree that that's not mentioned in this

25

Page 234 Page 236 1 section. 1 contacted the authors -- actually went a step ahead A. "Introduction"? 2 -- and got the data to conduct their analysis. 3 Q. I was trying to avoid a compound question. Q. No. "Background." 4 But the second question was they did include some of 4 A. In the abstract. 5 5 the data from O'Brien's study that came out of the Q. In the abstract. 6 A. Okay. 6 Nurses' Health Study. 7 Q. Okay. "Risk of ovarian cancer in women 7 MS. PARFITT: Objection to the 8 with frequent perineal talcum powder product is not 8 characterization of O'Brien. 9 well understood." Do you agree with that as a A. They included the data that was relevant to 10 starting point? 10 the question at hand. MS. PARFITT: Objection. 11 11 Q. Which was some of the data reported in 12 A. I mean, that is her context. There are 12 O'Brien. A. Yes. 13 studies prior to her that suggest that, you know --13 14 increased risk with frequent use, some. So I think 14 Q. Okay. Can we look at page 2529, Table 1? 15 the question is, like, you know -- I think it's a 15 A. Table 1, yeah. 16 context to begin a review. 16 Q. Okay. What are they doing in this table? Q. Okay. And then the final sentence of the A. They're providing an assessment of --17 17 18 "background," "The purpose of this study is to 18 Table 1; right? O. Yes. 19 estimate the association between frequent -- at 19 20 least two times per week -- perineal talcum powder 20 A. Quality assessment. Yeah. 21 use and ovarian cancer." Do you see that? 21 Q. Okay. Using the Newcastle-Ottawa scale? 22 A. Yes. 22 A. Yes. 23 Q. Okay. Would you agree with me generally Q. Is the Newcastle-Ottawa scale objective or 24 that the reliability of a meta-analysis is 24 subjective? 25 contingent on the selection of studies that it 25 A. I mean, any assessment is, you know -- is Page 235 Page 237 1 includes? 1 susceptible to interpretation. But here, too, A. Why a meta-analysis? A pooled analysis 2 they've included studies that are, you know, low 3 like O'Brien's and any study is dependent on the 3 quality, medium quality, high quality. So 4 data they decided to include, the analysis they set 4 obviously, anything is subject to interpretation. 5 up, what was the primary hypothesis. So it's not 5 And we can go through the questions and say 6 really either -- Woolen and it's Penninkilampi and 6 -- for example, the question on the Newcastle --7 everybody. 7 I'll give you an example why it is subject to Q. The reason why a meta-analysis is because 8 interpretation -- is adjusted for most reasonable 9 we happen to be looking at one right now. So you 9 confounder. So I could say "Well, age or parity." 10 would agree it's true of meta-analyses, as well as 10 And someone else would say "No. I want age, parity, 11 other things. 11 or oral contraceptive." So that's subject to 12 MS. PARFITT: Objection. Form. 12 interpretation. 13 Q. Dr. Singh, I'd appreciate it. I'm just Q. Can we look at page 2527, the first full 14 14 running short on time. I appreciate if you focus on 15 paragraph on the second column, "The four 15 the question asked. 16 prospective." 16 What study received the highest 17 A. Yeah. 17 Newcastle-Ottawa score here? Q. Can you just review that paragraph quickly? 18 A. O'Brien. 19 Then I'll ask you some questions. 19 Q. Okay. Do you agree with the assessment of 20 A. Yes. 20 giving O'Brien a higher quality score than the case Q. So I think you may have noted this in your 21 control studies? 22 report, but they did not include the pooled analysis A. Yes. 22

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23

24

Q. Okay.

A. And it also provides a significantly

25 increased risk. Independent of the whole analysis,

23 in O'Brien. But they did -- correct?

A. Yeah. So they had an etiologic question

25 about, you know, frequent use. And so they

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- 1 it reports a 40 percent risk for these.
- 2 Q. Again, we'll get to that. Again, I'd
- 3 appreciate if you just answer the questions.
- 4 The -- can you look back at the Taher
- 5 article that we talked about earlier, Taher 2019?
- 6 A. What's the number?
- 7 MS. PARFITT: It's number 24.
- 8 Q. When you get there, can you look at
- 9 Table 1, which spans page 89 and 90?
- 10 A. Table 2. Yeah.
- 11 Q. Table 1 on page 90.
- 12 A. Yeah.
- 13 Q. Whittemore -- well, first of all, this
- 14 table also evaluated studies using NOS. That stands
- 15 for Newcastle-Ottawa score?
- 16 A. Sure.
- 17 Q. Look at Whittemore, which is maybe a third
- 18 of the way down on page 90. What's the score there,
- 19 the Newcastle-Ottawa score they give it?
- 20 A. 4.
- 21 Q. Let's flip back to the Woolen article. You
- 22 can see they also GRADE the Whittemore article. Can
- 23 you see what they gave it there?
- 24 A. 7. Yeah.
- 25 Q. Okay. Do you know why it was given such a

- Page 240
- 1 quality studies, which they've done. So yes, rating
- 2 you can have -- I don't know if, you know, if I went
- 3 through what Taher did, I don't know if I would
- 4 exactly replicate their ratings. It may be 1 point
- 5 above or 1 point below.
- 6 Q. That was my next question. Have you
- 7 attempted to grade the qualities of the studies on
- 8 which you rely using the Newcastle-Ottawa scale?
- 9 MS. PARFITT: Objection. That question
- 10 was asked several hours ago, quantitative --
- 11 A. No. I did not do a Newcastle qualitative
- 12 because several of -- for example, if you go to
- 13 Penninkilampi, they graded all the studies are high
- 14 quality. So they didn't exclude any studies.
- 15 Q. Let's move to Table 2.
- 16 A. Of Taher --
- 17 Q. Of Woolen. You can put Taher away. We can
- 18 do that exercise for several more studies but --
- 19 A. This is done?
- 20 Q. Yes. We're done with that. Table 2,
- 21 Footnote 5.
- 22 A. Yeah.
- 23 Q. So you see that Dr. O'Brien provided
- 24 additional data that are included only in the
- 25 supplementary tables; right?

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1 higher rating in Woolen than the Taher article?

- 2 MS. PARFITT: Objection. Form.
- 3 A. I mean, they provide the reasons, you know,
- 4 selection, comparatively, and outcome -- exposure;
- 5 right? And that adds up to 7.
- 6 Q. Okay. Can you look at Wu, the Newcastle-
- 7 Ottawa score in that one in Woolen?
- 8 A. Yes.
- 9 Q. It's an 8?
- 10 A. Yeah.
- 11 Q. Can we flip back to Taher and --
- MS. PARFITT: Again, the page?
- 13 MR. MARTIN: Page 90, again.
- 14 Q. What did they give that same article?
- 15 A. 7.
- 16 Q. Okay.
- 17 A. So, I mean, those ratings, as we discussed
- 18 -- I was trying to explain -- and more important is
- 19 the analysis, which excluded the low-quality
- 20 studies, particularly Booth. And then even after
- 21 they excluded Whittemore, their estimates did not
- 22 change.
- So I think this issue of rating is
- 24 important. But perhaps even more important is
- 25 addressing what happens when you exclude the low-

- 1 MS. PARFITT: Let's read what it says.
- 2 Let's read it into the record.
- 3 Q. "O'Brien did not publish on daily exposure
- 4 for the National Health study participants.
- 5 However, these data were available, and O'Brien
- 6 provided these data for inclusion. The entirety of
- 7 these data were provided and are shared in the
- 8 supplementary table. We include data on women with
- 9 intact fallopian tubes to harmonize with other
- 10 publications."
- 11 MS. PARFITT: Thank you.
- 12 Q. Can we look at Supplemental Table 1, which
- 13 is in the next exhibit?
- 14 A. Yes.
- 15 Q. So you can see here that, as the footnote
- 16 suggested, there are data for all women and data for
- 17 women with patent fallopian tubes; right?
- 18 A. That is correct.
- 19 Q. Okay. In both cases, they're broken down
- 20 into nonusers, less frequent users, and daily users;
- 21 right?
- 22 A. That is correct.
- 23 Q. And so Woolen could have used the "daily
- 24 user" category among all women, which would have had
- 25 somewhere around 1200 ovarian cancer cases; right?

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1 MS. PARFITT: Objection to form.

- 2 A. Where is that number?
- 3 Q. I'm adding 706 plus 302 plus 216.
- 4 A. Yeah.
- 5 Q. Instead, they used, as we discussed, the
- 6 women with patent fallopian tubes; right?
- 7 A. That's correct.
- 8 Q. Okay. And both -- looking at daily users,
- 9 you'd agree that the both crude and adjusted hazard
- 10 ratios for daily users are higher among women with
- 11 patent fallopian tubes; right?
- 12 A. That is what O'Brien reported.
- 13 Q. Okay. And so by using the women with
- 14 patent fallop -- by using data only from women with
- 15 patent fallopian tubes, Woolen used a number that
- 16 was a higher risk ratio; right?
- 17 MS. PARFITT: Objection to the form.
- 18 Misstates what Woolen did.
- A. Yeah. I mean, they selected what, you
- 20 know -- based on the question about frequency, they
- 21 selected one of the ratios that they felt was
- 22 etiologically relevant -- not felt, but --
- 23 Q. They selected the higher of the two
- 24 available odds ratios.
- 25 MS. PARFITT: Objection. Misstates.

- Page 244 Q. We don't have time to read all the studies.
- 2 Let's just strike that question.
- 3 A. I didn't really understand that.
- 4 Q. Okay. It was not meant to be critical. I
- 5 was just trying to move on.
- A. I tried to understand it too.
- 7 Q. So turning back to the Footnote No. 5 in
- 8 Woolen that we read into the record a moment ago.
- 9 "We include data on women with intact fallopian
- 10 tubes to harmonize with other publications."
- 11 Can we look at the "methodology" section of
- 12 the abstract? And can you point me anywhere that
- 13 references patency in the inclusion criteria?
- MS. PARFITT: And you're limiting him 14
- 15 just to the abstract? There's a "methods" section
- 16 on the next page as well.
- 17 A. Give me one second. Let me just read it.
- 18 Yeah. So, I mean, to answer your question, you'd
- 19 have to go and look at the methods and publication
- 20 of primary data reporting on multiple times -- I'm
- 21 at "eligibility criteria and study selection,"
- 22 second paragraph.
- 23 Q. Yes.
- 24 A. So their criteria were --
- 25 MS. PARFITT: Go slowly. She's having a

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- A. That was what was available. 1
- 2 Q. So the answer is yes?
- 3 MS. PARFITT: Objection.
- 4 A. They selected the data that was 5 etiologically relevant to the question at hand.
- Q. It is the higher of the two odds ratios;
- 7 correct?
- 8 MS. PARFITT: Objection. He's answered
- 9 the question. Please.
- 10 Q. Let's look back at that table.
- 11 A. Same table?
- 12 O. Same table.
- 13 A. Yeah.
- 14 Q. Let's look at less frequent users, hazard
- 15 ratio for all women of 0.96 and a hazard ratio for
- 16 patent tubes of 1.04. Do you see that? "Less
- 17 frequent users"?
- 18 A. Okay. Yeah.
- Q. Okay. You'd agree that, if the next
- 20 category up was "daily users," some women in the
- 21 "less frequent users" category would have met the
- 22 greater-than-twice-a-week inclusion criteria?
- 23 MS. PARFITT: Objection. Form.
- 24 A. I don't -- I would have to go back and look
- 25 at how they define this. Give me a second.

1 hard time.

- A. "Selection criteria included publication of
- 3 primary data, reporting on multiple times per week
- 4 -- greater than two times per week -- perineal
- 5 exposure to talcum powder, including direct
- 6 application to the perineum, application to
- 7 underwear or sanitary napkins or on birth control
- 8 devices like diaphragms, at risk for malignancy.
- "And studies were also selected for
- 10 baseline quality, requiring a multi-value risk
- 11 adjustment, study-size cancers, and defined
- 12 researched methods."
- Q. Is there anything in what you just said
- 14 that references patency or tubal ligation?
- A. But -- yeah. I mean, it doesn't explicitly 15
- 16 mention that. But multi-value risk adjustment, you
- 17 know -- it doesn't even explicitly mention parity.
- 18 Doesn't mention oral contraception.
- When we do meta-analysis -- and I've done
- 20 65 of them -- you have to explicate your inclusion,
- 21 exclusion. All studies do not have the same
- 22 confounders they control for. So their etiologic
- 23 question was more than twice a week. And then once 24 they found that data, they have to choose.
- 25 Penninkilampi excluded many studies that,

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- 1 you know, didn't meet the criteria or had different
- 2 ratios of adjustment. We wouldn't exclude
- 3 Penninkilampi just because all the studies did not
- 4 adjust for the same confounder.
- 5 Q. I'm asking what I think is a simple
- 6 question. Do you see anything in the inclusion
- 7 criteria related to patency or tubal ligation?
- 8 MS. PARFITT: Objection. He's answered
- 9 the question.
- 10 A. I see it because I see multi-value
- 11 adjustment as not explicitly but implicitly looking
- 12 at the risk factors and -- which includes patency
- 13 and hysterectomy.
- 14 Q. So do you know if the other studies other
- 15 than O'Brien that are included in this meta-analysis
- 16 were limited to women with intact genital tracts?
- 17 A. Let's discuss the studies. I went and
- 18 reviewed that.
- 19 Q. Okay. We don't have time --
- 20 MS. PARFITT: Let him -- you asked a
- 21 question. Let him --
- 22 A. I'll tell you which ones did, which ones
- 23 didn't. This goes to the -- again, the science is
- 24 evolving. Some of the newer studies -- for example,
- 25 Schildkraut did assess for patency. Cramer reported

- ent 1 you have specific questions.
  - 2 Q. I appreciate that, and the reason I'm doing
  - 3 that is --
  - 4 MR. MARTIN: Can we go off the record
  - 5 again?
  - 6 (A break was taken)
  - 7 MR. MARTIN: All right. Before the
  - 8 break, we were talking about Woolen and talking
  - 9 about -- one of the studies that is included in the
  - 10 Woolen meta-analysis is a 2008 study by Wu, et al.
  - 11 So I'd like to mark that as the next exhibit.
  - 12 (2008 article by Anna H. Wu, et al.,
  - 13 Exhibit 28, marked)
  - 14 Q. Let's look at Table 2, which is on
  - 15 page 1411.
  - 16 A. Yes.
  - 17 Q. And you can see that frequency and duration
  - 18 of talc use is broken down into several categories.
  - 19 A. Sure.
  - 20 Q. The first is -- well, the first is less
  - 21 than 20 years -- excuse me -- less than or equal to
  - 22 20 years and less than or equal to 10 times a month.
  - 23 We'd all agree that that does not qualify for the
  - 24 selection criteria in Woolen; right?
  - 25 A. That is correct.

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- 1 data by patency. Some of the older studies did not.
- 2 So, first of all, they have to find the
- 3 etiologically relevant exposure category. Then if
- 4 that study reported data adjusting for patency, they
- 5 harmonize. It they can't harmonize based on
- 6 patency, the primary question is exposure category.
- 7 Q. So, again, the answer to the question is
- 8 that no, not all of the case control designs were
- 9 limited to women with patent reproductive tracts?
- 10 MS. PARFITT: Objection.
- 11 A. Yeah. That is correct. Some studies did
- 12 not adjust for it, especially the earlier studies
- 13 did not. But even excluding those earlier, low-
- 14 quality studies, the ratios are similar.
- 15 Q. Again, the answer was yes?
- 16 A. Yes. But because the -- that is typical of
- 17 a meta-analysis; not all studies will have the same
- 18 multi-value adjustment.
- 19 Q. One of the studies they look at is Wu;
- 20 correct?
- 21 A. That is correct.
- 22 Q. Okay. And this study is also individually
- 23 on your reliance list; right?
- A. I think I discussed this last time, but I
- 25 probably may have -- I mean, we can look at it, if

- Page 249
- 1 Q. Okay. The next one is less than or equal 2 to 20 years and between 10 and 30 times a month.
- 3 A. So it would be twice a week and --
- 4 Q. Does that qualify for the selection
- 5 criteria in Woolen?
- 6 A. It's one of the estimates that qualify.
- 7 There are others.
- 8 Q. Let's go to the -- what is the RR for that
- 9 one?
- 10 A. 16 -- 1.16 and 0.63 and 2.12.
- 11 Q. So there are others. Let's go to the next
- 12 one, less than 20 years and greater than 30 times a
- 13 month. That qualifies as well; right?
- 14 A. That is correct.
- 15 Q. And next one doesn't qualify -- right --
- 16 greater than 20 years but less than or equal to 10
- 17 times a month?
- 18 A. That is correct.
- 19 Q. Greater than 20 years and between 10 and 30
- 20 times a month?
- 21 A. That is correct.
- Q. Does that qualify?
- A. Which one? Second-to-last; right?
- Q. Second to last.
- 25 A. Greater than 20 years, greater than ten --

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1 yes. If it is greater than 10, yes.

- 2 Q. What's the risk ratio for that one?
- 3 A. 1.57, .99 to 2.5.
- 4 Q. In the final category here, greater than 20
- 5 years and greater than 30 times a month, that one
- 6 qualifies?
- 7 A. That is correct.
- 8 Q. Okay.
- 9 A. And that is the one they selected.
- 10 Q. You've preempted several of my questions,
- 11 but yes. The -- and that is the only one in which
- 12 the confidence interval does not cross 1 of the
- 13 various categories here. Do you agree with that?
- 14 A. Yes.
- 15 Q. Okay. And that is the only one that Woolen
- 16 selected; correct?
- 17 A. Yeah. And again, you know, this goes back
- 18 to the question. What is the question at hand?
- 19 Because meta-analysis -- Woolen, me, others,
- 20 Penninkilampi -- we have to make analytic choices.
- 21 When they say twice, you know -- more than twice a
- 22 week, that is a -- they are looking at any -- my
- 23 understanding is they are looking at any etiologic
- 24 relevant human exposure levels. So that's one.
- 25 The second point is -- and I'll -- let me
- Page 251
- 1 explain this. So, yes, these are eligible. They
- 2 select one. The second is, even, you know, if you
- 3 look at their meta-analysis forest plot, you will
- 4 see that the boxes for Woolen are -- the confidence
- 5 intervals are Y. It's a very small black box. The
- 6 biggest boxes are for NHS 2020 and Cramer.
- 7 So what -- again, that goes to the issue:
- 8 What is driving the estimates? It's Cramer and
- 9 O'Brien. So if -- even if they had selected, you
- 10 know -- say they selected a category, 1.57, this
- 11 would have only a minimal influence on their
- 12 meta-analytic estimate. And they further went ahead
- 13 and excluded Wu -- Wu, which they note in their --
- 14 you know, in the results, when excluding Wu, et al.,
- 15 which combined perineal administration of talc with
- 16 other methods, the summary pool ratio was 1.44, 95
- 17 percent CI, 29 -- 1.29 to 1.6.
- 18 So what this means is all analysts have to
- 19 make a choice. When I do a meta-analysis, I'm
- 20 comparing X drug to B. Sometimes there will be two
- 21 arms. I have to make a choice. And they made --
- 22 you're right. They selected the highest dose. But
- 23 that was etiologically relevant to human exposure.
- 24 And Wu is not contributing significant weight to
- 25 this analysis. Even if they chose -- went down, it

- 1 still will only be slightly attenuated.
  - 2 Q. Let's unpack that a little bit. So first
  - 3 of all, you'd agree with me they could have included
  - 4 all four estimates that met their inclusion
  - 5 criteria?
  - 6 MS. PARFITT: Objection. Misstates the
  - 7 testimony.
  - 8 A. How could they have included all four? I
  - 9 don't understand. Just because there are four
  - 10 categories? Is that the understanding?
  - 11 Q. Well, each of those categories represents a
  - 12 different set of women; correct?
  - 13 A. No.
  - 14 MS. PARFITT: Objection. Form.
  - 15 A. You cannot -- I'll explain why. Let me
  - 16 explain. Yeah. I mean, if they wanted, they could
  - 17 have, you know, done analysis by each category. But
  - 18 you never -- you would never include, like, Wu A, B,
  - 19 C, D, four different categories in one analysis
  - 20 because there is correlation, you know. All these
  - 21 studies are -- data are coming from the same
  - 22 analysis. You can't pool them together.
  - 23 You have to select -- so they could have
  - 24 done -- and we've talked that -- say 1.57 is
  - 25 relevant. They could have done that. But my answer

- 1 is that it wouldn't have -- they couldn't have
- 2 pooled all of them in that same analysis.
- 3 Q. Let's turn back to Wu -- to Table 2 in Wu.
- 4 A. Sure.
- 5 Q. And let's take, for example, the two
- 6 qualifying subsets for greater than 20 years.
- 7 A. Yeah.
- 8 Q. You see that? So the first one has 51
- 9 cases, 43 controls. Second one has 67 cases and 45
- 10 controls. They couldn't have pooled those two
- 11 numbers together and done 117 cases and 98 controls?
- 12 A. No. The reason is -- if you go to the
- 13 footnote -- one adjusted for race, ethnic -- so
- 14 these are the hazard ratios or adjusted hazard
- 15 ratios.
- So, you know, within a study, if -- you try
- 17 to pool, you know, your sort of correlated data.
- 18 Across studies, you can pool from -- but within that
- 19 study what could have, you know -- one approach
- 20 would have been look at different categories of
- 21 exposure, you know, in the main meta-analysis, not
- 22 pool these two categories together in that main
- 23 meta-analysis.
- 24 Q. They could have asked Dr. Wu for the
- 25 underlying data.

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- 1 MS. PARFITT: Objection. Form.
- 2 A. I don't -- yeah.
- 3 Q. Could they have asked Dr. Wu for the
- 4 underlying data?
- 5 MS. PARFITT: Objection. Form.
- 6 A. I mean, I don't know if that was the
- 7 approach they took. They were approaching it one
- 8 study. They want to look at one exposure category.
- 9 I don't think they were trying to disaggregate
- 10 exposure categories.
- 11 Q. Well, they did ask Dr. O'Brien for her
- 12 underlying data.
- 13 A. Yeah. Because -- they asked her because
- 14 she did not report it. Did not report it by that
- 15 exposure category. Here, they already reported.
- 16 They chose one. If they had gone one step further
- 17 and said "I'm not sure that Dr. Wu would have" --
- 18 they would have to give primary data. Then each of
- 19 them would have to be adjusted to be included in
- 20 that analysis. But looking at this table, you could
- 21 not include that.

7

22 Q. Let's -- okay.

A. That is correct.

10 is the size of the black box?

- A. No. I do this for a living, I mean.
- Q. Let's look back at the -- let's look back
- 25 at the Woolen forest plot. And when you mentioned

Q. Okay. And just so I understand your

4 opinion -- your basis for saying that Cramer and

5 O'Brien are the most important studies -- no. I'm

MS. PARFITT: Objection.

Q. Let me -- for saying that Cramer and

A. No. Yeah. That is because that is a

13 meta-analysis, but it's not only that. You can get

18 know, confidence interval as reflected in the, you

21 difference. If you look at O'Brien, it's 1.68 minus

24 ones that have wider confidence intervals are

25 contributing less weight, even though this is, as I

19 know, small box as well as -- but if you look at

For example, if you look at Wu, you're 17 talking about 1.34 to 3.23. So that's a wide, you

20 Cramer, you see it's 78 minus 20. That would be .58

So that's how weighting occurs. So the

14 even more precise because you can look at the

12 reflection of the underlying weight of the

15 difference in the confidence interval.

22 17. So it's a little more than that.

9 O'Brien contribute the most to the pooled estimate

- Page 256
- 1 understand, a random meta-analysis. So the weight 2 is being driven by these larger studies with precise
- 3 confidence intervals. I would have liked to see
- 4 weights. You know, when I do the meta-analysis, I
- 4 weights. Tou know, when I do the meta-analysis,
- 5 report weights.
- 6 Q. And by "weights," you mean a quantitative 7 assignment to each study?
- 8 A. Exactly. How much weight was this in the
- 9 analysis.
- 10 Q. Okay.
- 11 A. But I can tell you, looking at it, doing
- 12 this all the time, that that's what it is.
- 13 Q. Can we turn back to the PDQ?
- 14 A. Sure.
- 15 Q. It is Exhibit 7, just for your reference.
- 16 A. I got to find it now.
- 17 Q. Unsurprisingly, I'm going to ask you to
- 18 turn to the perineal talc exposure section of the
- 19 PDQ.
- 20 A. Let me find it. I'm going to find it.
- 21 What is it? 7?
- 22 Q. Exhibit 7.
- A. Got it. What is the page number for that?
- Q. It is not paginated.
- 25 A. Okay.

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1 the forest plot, you mean Figure 2 on page 2530? 1 Q. It's towards the end.

- 2 A. Endometriosis -- hormonal replacement
- 3 therapy, blah, blah, blah. Where is talc?
- 4 Q. Two pages behind that.
- 5 A. Got it.
- 6 Q. Okay. Thank you. Can we look at the
- 7 second paragraph of perineal talc exposure and
- 8 particularly the sentence beginning "A meta-analysis
- 9 of ten case control studies"?
- 10 A. Yes.
- 11 Q. Okay. "A meta-analysis of 10 case control
- 12 studies and a highly selected subset analysis of one
- 13 prospective cohort study found an association -- OR
- 14 1.47, 95 percent confidence interval, 1.31 to 1.65
- 15 -- among women who used perineal talc at least twice
- 16 a week." And you see that the -- that is to
- 17 Citation 10, which is the Woolen study; right?
- 18 A. That is correct.
- 19 Q. Okay. And you understand the highly
- 20 selected subset analysis of one prospective cohort
- 21 study to refer to the subset of O'Brien they used?
- A. That is correct.
- 23 Q. Okay. Next sentence, "The subset analysis
- 24 of the prospective study was inconsistent with the
- 25 main finding of the initial report." Do you agree

65 (Pages 254 - 257)

23

1 with that statement?

- 2 A. No. And let me explain why. So, you know,
- 3 the first statement is just statement of results and
- 4 includes -- talks about O'Brien.
- 5 The second statement is "The subset was
- 6 inconsistent with the main findings of the original
- 7 report." Well, the subset analysis of the
- 8 prospective study was the only one which actually
- 9 provided data on frequency by more than two times
- 10 per week. The original analysis provided data --
- 11 they define "frequency" as weekly. So you can't
- 12 compare twice a week versus weekly.
- So, you know, there's, like, apples to
- 14 oranges. O'Brien did not provide this data at the
- 15 time of the publication. So this is a different set
- 16 of data. So what are they comparing? When they say 16
- 17 "The subset analysis of this prospective study was
- 18 inconsistent with the main" -- I mean, this whole --
- 19 this issue is about frequency. And the frequency as
- 20 defined here is twice a week, which was not the
- 21 analysis in O'Brien.
- Q. So let me ask two questions to follow up on
- 23 that. You said in your answer, I believe, that the
- 24 subset used in the Woolen meta-analysis was the only 24
- 25 one that satisfied the frequency inclusion criteria.
  - Page 259
- 1 A. Two of them. Sister did. And Sister
- 2 had -- you know, they provided that Sister had,
- 3 like, what, two cases.
- 4 Q. I'm sorry. Yes. That's true. But -- that
- 5 is true. But in addition, Dr. O'Brien provided the
- 6 all-women data that also met the inclusion criteria;
- 7 right?
- 8 A. Which one? Where did you see that?
- 9 MS. PARFITT: Let's go back to that.
- 10 Q. The all-women data we talked about earlier
- 11 as opposed to the women with intact tubes data?
- 12 A. Yes. Yes. Yeah. But -- let me clarify.
- 13 I don't think that this interpretation,
- 14 Reference 11, when they're talking about -- I think
- 15 they are referring to -- they have -- I don't think
- 16 this refers to that table of the Woolen report.
- 17 I think this refers to the subset analysis
- 18 of the prospective cohort study was inconsistent
- 19 with the main findings of the original report, which
- 20 is when they go back to O'Brien.
- 21 Q. Right.
- 22 A. But O'Brien's frequency is weekly. So how
- 23 are you going to compare?
- Q. I was simply asking a follow-up question to
- 25 something you said in your answer.

- 1 Do you know what percentage of the O'Brien
- 2 sample was ultimately included in Woolen?
- 3 A. I didn't calculate the percentage. I mean,
- 4 whatever the sample was, you know, frequency was
- 5 relevant.
- Q. Can we turn back to your report?
- 7 A. Page?
- 8 Q. 6. Final full paragraph, starting about
- 9 half to two thirds of the way through that
- 10 paragraph, "Among the five."
- 11 A. Final -- Woolen?
- 12 Q. No. It's page 6.
- 13 A. Okay. 6. Yeah. My report, new report?
- 14 Q. Of your new report?
- 15 A. Yeah. Go ahead.
  - Q. Okay. "Among the five cohort studies
- 17 included in Health Canada's review, they reported no
- 18 statistically significant associations between
- 19 genital talcum powder use and risk of epithelial
- 20 ovarian cancer. But the majority of cohort studies
- 21 also reported an elevated risk consistent with the
- 22 case control studies." By "elevated risk," do you
- 23 mean a point estimate above 1.0?
  - 4 A. That is correct.
- 25 Q. Okay. Do you consider any point estimate

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1 above 1.0 to represent an elevated risk?

- 2 MS. PARFITT: Objection. Asked and
- 3 answered many hours ago exhaustively.
- 4 A. I think we had this discussion. Is it 1.2,
- 5 1.3? I don't have -- you know, I think I sort of
- 6 take an opinion on what the American Statistical
- 7 Association has said. It's really explained in
- 8 detail in my previous report.
- 9 Q. You're on the editorial board of two new
- 10 journals since your previous report, Frontiers in
- 11 Drug Safety and Frontiers in Primary Care and Family
- 12 Medicine.
- 13 A. That is correct.
- 14 Q. Do you know if those journals require
- 15 submissions of P values or confidence intervals?
- 16 A. All journals require.
- 17 Q. Okay.
- 18 A. Submission does not mean, you know -- they
- 19 also require cautious interpretation. And so
- 20 submission of P-values is -- what does that P-value
- 21 mean? And P-values are just a statement that your

Q. Just to be clear, the answer to my question

- 22 data -- the probability of obtaining data as a more
- 23 extreme when your null hypothesis is true.
- 25 is yes, they do?

66 (Pages 258 - 261)

24

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- 1 A. Yes.
- 2 Q. Can we turn back to Health Canada?
- 3 A. Which one is that? 25.
- 4 MS. PARFITT: Absolutely. Right.
- 5 Q. Let's look at the biological plausibility
- 6 discussion in Health Canada. Which is on page --
- 7 MR. MARTIN: Can we go off the record 8 for a moment.
- 9 (A break was taken)
- MR. MARTIN: Back on the record.
- 11 Q. Do you see the final -- well, do you see
- 12 the final paragraph of that section, the second of
- 13 two, "Collectively, there is significant exposure
- 14 information lacking to permit a fulsome assessment
- 15 of biological gradient"?
- 16 A. Yes. But in the Taher report, they already
- 17 provided the studies that provide evidence of, you
- 18 know --
- 19 Q. So do you agree --
- 20 MS. PARFITT: Wait. Wait. Please let
- 21 him finish.
- 22 Q. I apologize.
- 23 A. That is why my weight on dose response was,
- 24 you know, was qualified. It doesn't mean there
- 25 cannot be an assessment. You have -- in fact, if
  - \_\_\_\_\_
- Page 263 1 one had not performed a fulsome assessment, then I
- 2 would not -- you know, I think that report should
- 3 not -- you know, report would be improper because
- 4 you have to perform -- so there is enough data to
- 5 perform an assessment. But whether you have a
- 6 gradient or not, you have to explain.
- 7 You know, there are some studies that
- 8 provide exposure response based on how these are
- 9 measured, other studies that don't. So I think this
- 10 sentence is not incompatible with their own, you
- 11 know, report -- I mean, in the study.
- 12 Q. I'd like to move to the previous paragraph
- 13 and, in particular, draw your attention to several
- 14 of the citations there, particularly in the first
- 15 parenthetical, Ballman 2019, Diette 2019, and -- in
- 16 the last large parenthetical -- Moorman 2018,
- 17 Siemiatycki 2018, Singh 2018, Smith-Bindman 2018,
- 18 Wolf 2018. Do you know what those citations are?
- 19 A. Yeah. They are citations to expert reports
- 1) A. Tean. They are chanons to expert reports
- 20 in previous -- some of them. I mean, I don't know
- 21 if all of them are. Seems like it is.
- 22 Q. That is correct. Are you -- is it typical
- 23 in scientific literature to cite litigation expert
- 24 reports?
- 25 MS. PARFITT: Objection. Form.

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- 1 A. I will provide you examples. I mean, if
- 2 you look at a tobacco litigation, that has produced
- 3 hundreds of manuscripts. If you look at the opioid
- 4 litigation, there's an archive at UCSF that has
- 5 produced at least -- I wouldn't say "hundreds."
- 6 So, you know, I would recommend that J&J
- 7 come to agreement with -- whenever this matter is
- 8 settled to make these documents available. And I'm
- 9 happy to facilitate that. Exactly.
- 10 Q. My question is not related to
- 11 confidentiality. My question is have you in your
- 12 academic work cited litigation reports as support
- 13 for -- as scientific support?
- 14 MS. PARFITT: Objection. Different
- 15 question.
- A. Not me personally. You asked is there --
- 17 you know, the first question prior to that -- maybe
- 18 you can read that -- the question.
- 19 Q. I agree. It's a different question. It is
- 20 a different question.
- 21 A. You asked, you know, "Are there citations
- 22 to litigation?" And I provided you many examples:
- 23 Vioxx, of, you know, tobacco, of opioids. So as
- 24 long as -- you know, again, you have to evaluate.
- 25 Both reports were considered.

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- 1 Q. So can you answer the question that I 2 asked?
- 3 A. Me? No, I have not. No. But, you know,
- 4 in this report I have. In my report I have.
- 5 Q. Correct. But in your academic work you
- 6 have not.7 A. No.

9

- 8 Q. Can we turn to page 17?
  - MS. PARFITT: Health Canada?
- 10 MR. MARTIN: Health Canada.
- 11 A. Okay. Health Canada. Yeah. I'm there.
- 12 Q. Second half of the page.
- 13 A. Yes.
- 14 O. Second sentence of the second-to-last
- 15 paragraph, "There are a number of different tumor
- 16 types with characteristic histological (verbatim)
- 17 features, distinctive molecular signatures, and
- 18 disease trajectories. Moreover, these tumors are
- 19 heterogeneous and can arise from different tissues
- 20 of the female reproductive tract, including the
- 21 fallopian tube epithelium."
- 22 Do you agree that different subtypes of
- 23 ovarian cancers have different molecular signatures?
- 24 A. Right. I'm not a molecular scientist. I
- 25 know that different -- what I know is that different

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- 1 types of epithelial ovarian cancer can arise. For
- 2 example, endometrioid can arise from different;
- 3 clear-cell can arise from different; mesotheliomas
- 4 can arise from different; you know, serous ovarian
- 5 cancers can arise from different.
- 6 I don't know what they mean by "molecular
- 7 signatures." I don't really understand. That's not
- 8 my area of expertise.
- 9 Q. Can we turn to page 45 of Health Canada?
- 10 A. Yes.
- 11 Q. Final sentence of the first paragraph --
- 12 this is sort of where they sum things up -- "While
- 13 there may not be consensus within the scientific
- 14 community regarding the" --
- MS. PARFITT: One second.
- 16 A. Where is that? Page 45; right?
- 17 Q. Yes.

4

5

7

A. Yes.

- 18 A. Final sentence of the --
- 19 Q. First paragraph.
- MS. PARFITT: Up here.
- 21 A. Okay. Yeah. Go ahead.
- Q. "While there may not be consensus within
- 23 the scientific community regarding the

3 consistent with your conclusion?

6 within the scientific community?

- 24 interpretation of the epidemiological information,
- 25 after weighing the available lines of evidence, the

1 assessment determined that the current data are

Q. Do you agree that there is not consensus

MS. PARFITT: Objection. Form.

8 A. Well, that's what they, you know,9 interpreted. But after reviewing the whole body of

10 evidence, they conclude and I conclude that the

11 current data are indicative. There's, you know,

Q. Understood. I'm just trying to get youropinion on the state of scientific opinion. Do you

A. The scientific -- I don't really -- I mean,

16 believe there's a scientific consensus about these

19 you know, everybody has their opinions. I think

21 cancer? It could be talc and endometrial cancer. I

I mean, talc and -- you know, if it's

24 smoking, a lung cancer -- obviously, it's not to

25 that level. But, you know, there is enough

20 that -- why make it specific to talc and ovarian

22 think that's not relevant to causality.

12 different scientific consensus about lots of

13 different things. But that's what they state.

2 indicative of a causal effect." Is that sentence

- Page 268
- 1 established scientific consensus. I mean, you look
- 2 at the OCAC consortiums. You look at, you know, the
- 3 studies published.
- 4 So it's like "What is the threshold" when
- 5 you say there's scientific consensus. How many
- 6 scientists do you need? Hundred? Five hundred?
- 7 We've had 30 studies. Do you need a hundred? I
- 8 don't know. I don't have a level when I can say
- 9 there's scientific consensus.
- 10 Q. Are you aware of any -- are you aware of
- 11 any regulator in the United States that has found
- 12 talc -- peroneal talc use to constitute -- cause
- 13 ovarian cancer?
- 14 MS. PARFITT: Objection. Form.
- 15 A. Yes.
- 16 Q. Which one?
- 17 A. The EPA.
- 18 Q. Is that --
- 19 A. Not -- yeah. EPA. The recent update.
- 20 Q. Your opinion is that this document
- 21 represents the EPA's opinion that talc use causes
- 22 ovarian cancer?
- 23 A. Yes.
- 24 Q. Okay.
- 25 A. And we can read that if you want.

Page 26

Q. We have 12 minutes left. I don't think we

1 Q 2 can.

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- 3 A. You asked a question.
- 4 Q. I understand.
- 5 A. Got to get it in the record.
- 6 O. Let's talk about Fletcher 2019. We have to
- 7 mark it.

14

- 8 MR. MARTIN: It's Harper, Harper 2019.
- 9 MS. PARFITT: As we're going on the
- 10 track here, final track, you're picking up speed.
- 11 She is going to be losing speed. We'll have a
- 12 disconnect here. You're fired up.
- 13 THE WITNESS: I'm trying to --
  - MS. PARFITT: I know. It's hard for her
- 15 to get your words.
- 16 (2019 article by Amy K. Harper, et al.,
- 17 Exhibit 29, marked)
- 18 Q. This is published in a journal called
- 19 Edizioni Minerva Medica. Do you see that?
- 20 A. Yes.
- 21 Q. Prior to including this article in your
- 22 expert report, had you ever heard of that journal?
- 23 A. Actually, I've heard of the Minerva
- 24 journals. I don't know about this Edizioni Minerva
- 25 Medica, but I know about the Minerva group of

68 (Pages 266 - 269)

17 issues?

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- 1 journals. I don't know specifically this journal.
- Q. Can we look at the final page?
- 3 A. Okay.
- Q. "Funding" section, "A portion of Ghassan M.
- 5 Saed's time conducting this research was paid for by
- 6 the lawyers representing plaintiffs in the talcum
- 7 powder litigation." We've talked about this a lot.
- 8 That doesn't affect your view of the reliability of
- 9 the article?
- 10 MS. PARFITT: Objection.
- A. You know, to the extent that I talked about
- 12 it, I didn't say that it doesn't. I said it's an
- 13 issue of interpretation. Obviously, I have to look
- 14 at the methods. And, you know, I'm aware that they
- 15 were the authors in this.
- Q. Can we look back on the first page in the
- 17 abstract? Do you see where it says "72 hours of
- 18 treatment"?
- A. Yes. 19
- 20 Q. Okay. And do you see where it says that
- 21 "exposure to talcum powder induces malignant
- 22 transformation" in the "conclusion" section?
- 23 A. In the abstract?
- Q. In the "conclusion" section of the 24
- 25 abstract. Yes.

1

- 1 reliance list reflect everything that you relied
- 2 upon in the drafting of your 2023 report?
- A. Drafting, yes. But then I have
- 4 subsequently reviewed other things that was provided
- 5 to -- you know, since November.
- Q. Those were the documents that were provided
- 7 to us on Monday?
- A. Yeah.
- Q. Okay. Is every document that you have
- 10 reviewed in forming your opinions included in one of
- 11 the following three places: The 2019 reliance list
- 12 -- excuse me -- the 2018 reliance list, the 2023
- 13 reliance list, and the documents produced on Monday?
- A. Yeah. I cannot think of any other
- 15 document.
- 16 Q. Can we return to the Narod paper very
- 17 briefly?

24

- 18 A. Which is number?
- 19 Q. That is -- I can give you an unmarked copy
- 20 if you can't find it.
- 21 MS. PARFITT: It's 22.
- 22 A. It's probably there somewhere.
- 23 Q. Do you mind just referencing my copy?
  - MS. PARFITT: I've got it right here.
- 25 Q. Great. Thank you. Can you look at the

- A. Yes.
- Q. Okay. Does 72 hours strike you as a short
- 3 period of time in which to observe malignant
- 4 transformation?
- 5 MS. PARFITT: Objection. Form.
- A. Yeah. So, again, I'm not, you know -- I
- 7 can interpret the studies. And I have, you know,
- 8 looked at them. And they are -- experiments seem
- 9 reasonable. And whether these occur -- malignant
- 10 transformations occur in 72 hours or takes 400
- 11 hours, I don't know that. I mean, it seems, you
- 12 know, reasonable on the surface. And I relied on
- 13 that to make my assessment.
- 14 Q. But it's not your area of expertise?
- A. Yeah. I wouldn't say that this, you know
- 16 -- how long does it take to induce malignant
- 17 transformation.
- Q. I just want to do some final housekeeping
- 19 the last few minutes. Can you look at your new
- 20 reliance list at the end of your 2023 report?
- 21 A. Yeah.
- 22 Q. Okay.
- 23 A. Which is which page? Yeah.
- 24 Q. Are the 75 articles on this reliance list
- 25 everything that you -- do the 75 articles on this

- 1 last paragraph?
- 2 A. Taher or Narod?
- 3 O. Narod.
- 4 MS. PARFITT: I'm sorry.
- 5 Q. I got it here. Can you just look at the
- 6 last paragraph there?
- 7 A. Last -- second page, last paragraph?
- Q. Second page, last paragraph. Do you see
- 9 the third sentence, "I don't think we should try to
- 10 ascribe any particular case of ovarian cancer to
- 11 prior talc use"? See that sentence?
- 12 A. Yes.
- 13 Q. Do you agree with that sentence?
- 14 A. I mean, just --
- 15 MS. PARFITT: Objection to the form.
- 16 Please go ahead.
- 17 A. Just prior to that, they say "In the
- 18 interest of public health, I believe we should
- 19 caution women against using genital talcum powder."
- 20 But then they, you know -- so I -- that, to me,
- 21 means that they're ascribing risk to genital talcum
- 22 powder so -- but then they get into this particular
- 23 case -- any particular case.
- 24 So that would depend on how you -- what is
- 25 in that case, what is the age, what is the sex, what

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- 1 is oral contraceptive use, what is the family
- 2 history, what is the genetic markers.
- I mean, blanket, you cannot say that --
- 4 this case. But I think someone with more experience
- 5 as a gynecologic oncologist could look at the data
- 6 and can ascribe or can refute that. This does not
- 7 occur.
- 8 Q. So you don't agree with that sentence?
- A. Yeah.
- 10 O. As a --
- 11 A. I don't think we should to ascribe -- I
- 12 think they are -- you know, they should have been
- 13 much more nuanced in this, that this requires
- 14 contextual considerations.
- Q. Do you know who any of the bellwether
- 16 plaintiffs in the federal MDL are?
- 17 A. No.
- Q. Do you know who any of the trial plaintiffs
- 19 in the New Jersey MCL are?
- 20 A. I don't know.
- 21 Q. The New Jersey state court proceedings.
- 22 A. No, I don't. I don't think so.
- 23 Q. You're not offering an opinion on the
- 24 causation of any individual person's ovarian cancer?
- 25 A. No. That's not my area of expertise.
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- Q. You don't intend to do so in this
- 2 litigation?

1

- 3 A. No. That's not my area of expertise.
- MR. MARTIN: Can we go off the record? 4
- 5 I'll review my notes.
- (A break was taken)
- 7 MR. MARTIN: Back on the record.
- 8 Nothing further from me at this point, Dr. Singh.
- 9 THE WITNESS: Thank you.
- 10 MS. PARFITT: Dr. Singh, I just have a
- 11 few questions as part of the follow-up.
- 12 **EXAMINATION**
- 13 BY MS. PARFITT:
- Q. Dr. Singh, you were asked questions within
- 15 the last hour with regard to any regulatory body
- 16 here in the United States that has addressed the
- 17 issue of asbestos in talc and ovarian cancer. Do
- 18 you remember that series of questions?
- 19 A. That is correct.
- Q. All right. And I believe you referenced
- 21 the EPA; is that correct?
- 22 A. That is correct.
- Q. Let me show you what we will have marked as
- 24 Exhibit No. 30.
- 25 ("EPA Asbestos Part 1; chrysotile

- Page 276 1 asbestos; regulation of certain conditions of use
  - 2 under the Toxic Substance Control Act, TSCA,"
  - 3 document, Exhibit 30, marked)
  - Q. It's entitled "EPA Asbestos Part 1;
  - 5 chrysotile asbestos; regulation of certain
  - 6 conditions of use under the Toxic Substance Control
  - 7 Act, TSCA." Do you see that?
  - A. Yes.
  - Q. The agency is the Environmental Protection
  - 10 Agency. Do you see?
  - 11 A. Yes.
  - 12 Q. You see it says "Final rule" at the top?
  - 13 A. Yes.
  - 14 Q. Okay. Want you to turn first to the
  - 15 summary. I'm going to reference a couple of
  - 16 sections here. Go to the summary on page 1.
  - 17 A. That is correct.
  - Q. It states "The Environmental Protection
  - 19 Agency -- EPA or the agency -- is issuing this final
  - 20 rule under the Toxic Substance Control Act to
  - 21 address to the extent necessary the unreasonable
  - 22 risk of injury to health presented by chrysotile
  - 23 asbestos based on the risks posed by certain
  - 24 conditions of use.
  - 25 "The injuries to human health include

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- 1 mesothelioma and lung, ovarian, laryngeal cancers
- 2 resulting from chronic inhalation exposure to
- 3 chrysotile asbestos."
- 4 Is this the -- one of the sections of the
- 5 EPA report that you were referring to earlier when
- 6 counsel asked you what you were relying on for
- 7 purposes of your opinion that the EPA had made a
- 8 final rule regarding causation and asbestos and
- 9 talc?
- 10 MR. MARTIN: Objection.
- A. No. Yeah. That was one of the segments 11
- 12 but sort of another pertinent section is on page 14.
- 13 Q. Tell us about that.

18 lung, and ovarian.

- 14 A. The last -- at the bottom of page 14 we
- 15 have -- so the first one you presented is summary.
- 16 Talks about asbestos as a cause of, you know, risk
- 17 factors, various cancers including mesothelioma,
- But here at the end of page 14, the EPA
- 20 says, additionally, some talc deposits and articles
- 21 containing talc have been shown to contain asbestos.
- 22 Thus, EPA recognizes that use of talc may present
- 23 the potential for asbestos exposure.
- 24 Q. What significance, if any, does that have
- 25 to your opinions in this case?

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- A. Well, it's, you know -- my opinions are --1
- 2 overall causal opinion is that, you know, talc is --
- 3 talc is causally related to development of ovarian
- 4 cancer, not predicated on -- necessarily on the
- 5 basis of asbestos. But now, more and more evidence
- 6 is emerging such as -- you know, this was published
- 7 after I submitted my report -- that further enhances
- 8 the evidence on biologic plausibility segment on --
- 9 as one more further in the chain of evidence about
- 10 talc and ovarian cancer.
- Q. All right. If you would turn as well to
- 12 page 20 of the report.
- 13 A. My report?
- 14 Q. The EPA report.
- 15 A. Okay. Yes.
- Q. Subsection 1, it's called "Description of 16
- 17 unreasonable risk."
- 18 A. Yes.
- 19 Q. If you would read -- let me just ask the
- 20 question -- read to yourself the first half of that
- 21 paragraph?
- 22 A. Yes. "The health endpoint driving EPA's
- 23 assessment" -- "determination" -- I'm sorry -- "of
- 24 unreasonable risk for chrysotile asbestos under the
- 25 conditions of use is cancer from inhalation

- 1 the potential additional exposure to PFAS that might 2 result from this action."
- Do you have an opinion to a reasonable
- 4 degree of scientific certainty that indeed
- 5 chrysotile asbestos is a known human carcinogen that
- 6 causes mesothelioma, lung, ovarian, and laryngeal
- 7 cancers?
- 8 A. I mean, I think that is indisputable, that,
- 9 you know, asbestos is a carcinogen and specifically
- 10 for ovarian cancer. I mean, you know, did I do the
- 11 causal assessment? No. But IARC has done it. EPA
- 12 has done it. Others have found it. I would say the
- 13 fact that asbestos is an ovarian carcinogen is, you
- 14 know -- as we were talking about scientific
- 15 consensus, I mean, that is beyond dispute.
- Q. And your opinions today with regard to
- 17 talcum powder, do they consider the fact -- are they
- 18 based upon the fact that talc contains asbestos?
- A. Yeah. I mean, as I noted in my report --
- 20 earlier report that, you know, studies have
- 21 described that, you know, investigators have found
- 22 and FDA has found and testing by Drs. Longo and
- 23 others have found the presence, that talc, you know,
- 24 contains asbestos.
- 25 Q. But your opinion in this case is that

- 1 exposure. Unreasonable risk includes the risk of
- 2 mesothelioma and lung, ovarian, and laryngeal
- 3 cancers from chronic inhalation exposure."
- Q. Similarly, what, if any, significance do
- 5 you attach to that ruling by the EPA as to the
- 6 opinions you've given in this case?
- A. Yeah. So, as I stated in my earlier report
- 8 in '18, that this is one other, you know, one --
- 9 another pathway -- a plausible pathway. If talc
- 10 contaminated with asbestos is inhaled, that may be
- 11 another potential pathway by which there's an
- 12 increased causal risk of ovarian cancer.
- Q. Okay. And lastly, if you'll turn to
- 14 page 92 and 93 of the EPA report that you've
- 15 referenced earlier as a source supporting your
- 16 statement that a governmental regulatory agency has
- 17 opined on these issues. If you go to the bottom of
- 18 that page, if you will.
- 19 A. Yes.
- 20 Q. Bottom of 92, it starts "EPA believes that
- 21 the benefits" -- "EPA believes the benefits of
- 22 removing chrysotile asbestos, a known human
- 23 carcinogen that causes cancer, mesothelioma, lung,
- 24 ovarian, and laryngeal cancer, from continued use in
- 25 the United States are significant enough to outweigh

- Page 281 1 talcum powder can cause ovarian cancer based upon
- 2 the fact that talc can contain asbestos or may not
- 3 contain asbestos; correct?
- A. Yeah. My causal opinion is, you know, I --
- 5 to the extent I did, I mirrored that I'm not
- 6 predicating my opinion on the presence of asbestos.
- 7 But I'm, you know -- there are studies that -- and I
- 8 cited those studies. But now with the EPA ruling
- 9 and -- it is becoming more and more likely that that
- 10 is one more pathway that, you know, is suggesting 11 causal risk between talc and ovarian cancer.
- 12 Q. All right, Dr. Singh. You were -- let me
- 13 show you, if I will, Exhibit No. 24, the Tanha
- 14 article entitled "Investigation on factors
- 15 associated with ovarian cancer: An umbrella review
- 16 of systematic review and meta-analysis." That
- 17 was --
- 18 MR. MARTIN: Which exhibit is this? I'm
- 19 sorry.
- 20 MS. PARFITT: Exhibit 24.
- 21 Q. Let's pull yours here. Tanha?
- 22 A. That's the umbrella review?
- 23 Q. Yes. Here we go? Let me show you Exhibit
- 24 No. 24, Tanha. If I can direct your attention,
- 25 please, to page 15 of 17. Let me know when you get

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1 there.

- 2 A. Yes.
- 3 Q. All right. You'll recall that counsel
- 4 asked you a question with regard to whether or not
- 5 you agreed or disagreed with the statement that
- 6 states "The ovarian carcinogenesis mechanism of
- 7 perineal talc use has remained unclear." Do you
- 8 remember being asked that question?
- 9 A. Yes.
- 10 Q. What counsel did not read to you is the
- 11 following: "Based on a hypothesis, however, as an
- 12 external stimulus, talc can ascend from the vagina
- 13 to the uterine tubes and trigger a chronic
- 14 inflammatory response, further promoting the OC" -
- 15 ovarian cancer -- "development, cellular injuries,
- 16 and oxidative stress, and local elevation of
- 17 inflammatory mediators -- for example, cytokines and 17
- 18 prostaglandins -- could be mutagenic, thus
- 19 encouraging carcinogenesis." Do you agree or
- 20 disagree with that statement?
- 21 A. Yeah. And I have cited a slight different
- 22 version in my testimony about Dr. O'Brien providing
- 23 exactly -- if it's a slight difference on nuance,
- 24 you know -- the same suggestion of mechanism of
- 25 carcinogenesis.

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- 1 Q. Let me show you that. I'm not sure it was 2 marked. It's Ogunsina and O'Brien.
- 3 MS. PARFITT: If it was not marked.
- 4 we'll mark it as Exhibit 31.
- 5 (Article by Kemi Ogunsina, M.D., et al.,
- 6 Exhibit 31, marked)
- 7 MR. MARTIN: Do you have a copy of it?
- 8 MS. PARFITT: We do. I think we have
- 9 three.
- 10 Q. Let me show you what we've marked
- 11 Exhibit 31. It's the Ogunsina and Dr. Katie O'Brien
- 12 article and some others.
- 13 A. Yeah.
- 14 Q. You referenced in speaking about the Tanha
- 15 article that -- the position that the Tanha editors
- 16 had taken as it relates to how talc can migrate and
- 17 cause this chronic inflammatory response, promoting
- 18 these cellular injuries, oxidative stress, and local
- 19 reason of inflammatory mediators. What is the
- 20 position of the O'Brien and Ogunsina article with
- 21 regard to that same opinion?
- A. They cannot be more explicit than they are
- 23 here in page 1 -- 665 E1: "Talc is a poorly soluble
- 24 particle" ---
- MR. MARTIN: What page?

1 A. It's the first page, "introduction."

- 2 "Introduction," third column, third line, "Talc is a
- 3 poorly soluble particle. And animal models have
- 4 shown that, once deposited onto epithelial cells, it
- 5 can cause chronic inflammation, leading to a series
- 6 of mutagenic events" -- exactly the same that we
- 7 were seeing in the other -- "and this effect is
- 8 worse in talc contaminated with asbestos, a known
- 9 carcinogen" and the cite reference 19, which is the
- 10 IARC working group.
- Not only that, you know, we had a
- 12 discussion earlier about "Well, you know, there's no
- 13 evidence of migration in Health Canada." But that
- 14 is not entirely correct, because if you look at
- 15 page 22 of -- going to page 22 of --
- 6 Q. Health Canada?
- A. -- Health Canada, the first paragraph they
- 18 discuss the studies. And they say that "This lends
- 19 support to the idea that externally applied talc can
- 20 migrate from the perineal and, therefore, the
- 21 Johnson study." So it's not that Health Canada is
- 22 saying it cannot migrate.
- 23 MR. MARTIN: Was this produced to us on
- 24 Monday?
- MS. PARFITT: It was.

- 1 MR. MARTIN: I do not see it anywhere.
- 2 MS. PARFITT: Should be in the Dropbox.
- 3 A. The Health Canada, I'm sure, is there.
- 4 MS. PARFITT: What I'd like to do next
- 5 is have marked as Exhibit No. 32 an article entitled
- 6 "The association between douching, genital talc use,
- 7 and the risk of prevalent and incident cervical
- 8 cancer" by Katie O'Brien, Weinberg, D'Aloisio --
- 9 D-a-l-o-i-s-i-o -- Moore, and Sandler. Counsel,
- 10 here's a copy.
- 11 (Article by Katie M. O'Brien, et al.,
- 12 Exhibit 32, marked)
- 13 Q. All right, Dr. Singh. Is Exhibit 32 an
- 14 article that you've previously reviewed for purposes
- 15 of your opinions in this case?
- 16 A. Yes.
- 17 Q. Okay. And what, if any, significance does
- 18 this article, O'Brien, Sandler, et al., have on your
- 19 opinions of your -- excuse me -- talcum powder
- 20 exposure can cause ovarian cancer?
- 21 A. So if you go to the second page of the
- 22 article, 2211114836, they are write in the top just
- 23 above the methods, "Genital talc use could also
- 24 plausibly contribute to cervical cancer risk. Talc 25 applied to underwear, sanitary napkins, diaphragms,

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- 1 directly" -- "can enter the vagina and travel up the
- 2 reproductive tract. Talc particles may act as
- 3 irritants, inciting an inflammatory response and
- 4 potentially affect individuals' susceptibility and
- 5 response to HPV. Additionally, more severe
- 6 effects" ---
- 7 Q. Excuse me. You missed a word.
- 8 A. "Or more severe effects could occur" --
- 9 Q. I'm sorry. You missed another word. Just
- 10 so the record's correct, did you say "adverse"?
- 11 A. Yeah. "Adverse affects could occur through
- 12 the talc containing asbestos, a known carcinogen
- 13 sometimes mined in the same locations."
- 14 Q. Continue.
- 15 A. And the epidemiological literature supports
- 16 a possible positive association between genital talc
- 17 use and ovarian cancer, in which they cite their own
- 18 study without any qualification about patent or
- 19 nonpatent tubes. So that's -- Reference 35 is
- 20 O'Brien, et al., the pooled analysis we've been
- 21 discussing.
- 22 Q. The 2020 article?
- 23 A. Yes.
- Q. I believe I asked you what the
- 25 significance, if any, of this article was to your

- 1 fibroids; correct?
  - 2 A. Yes.
- 3 Q. It does not evaluate the relationship -- it
- 4 does not directly evaluate the relationship between
- 5 genital talc use and cancer; correct?
- A. Yeah. And this is a contextual study. And
- 7 partly why I looked at it and -- I looked at it was
- 8 I was interested in Dr. O'Brien's interpretation of
- 9 statistical significance. In fact, one of his other
- 10 studies, which was the Sister Study in which he
- 11 thought -- you know, she interprets positive
- 12 associations for hazard ratios that are not
- 13 significant, you know, the update of the Sister
- 14 Study by Chang.
- 15 So I wanted to -- I was interested in how
- 16 does she think about other cancers. So here, I see,
- 17 you know -- in fact, this goes to uterine fibroids.
- 18 There's knowing that -- it is not specific to talc
- 19 and ovarian cancer. But it provides context.
- 20 That's all.
- 21 O. It does not measure cancer outcomes.
- 22 A. No.
- 23 Q. Okay. Can we look at the EPA document,
- 24 Exhibit 30, and can we look at the first page?
- 25 A. Page?

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- 1 opinions.
- 2 A. Yeah. The significance is, first of all,
- 3 Dr. O'Brien, you know -- I was shown an article.
- 4 She talks about an experimental model. She has in
- 5 multiple places, you know, mechanisms and models of 5
- 6 how talc migrates, causes -- we're talking about
- 7 migration, inflammation, contamination with asbestos
- 8 causing -- she has a real outline of the model.
- 9 She couldn't have described it better than
- 10 myself and also interprets her own article without
- 11 any qualification for patent tubes as a possible
- 12 positive association.
- MS. PARFITT: I don't have any further
- 14 questions, subject to counsel.
- 15 MR. MARTIN: Let me just review a couple
- 16 of things. I'll see if I have another question.
- 17 (A break was taken)
- MR. MARTIN: Back on the record.
- 19 Q. Can I direct your attention to Ogunsina,
- 20 Exhibit 31?
- 21 MR. MARTIN: And I do just want to put
- 22 on the record that, as a result of a syncing error,
- 23 that was not produced to us on Monday. So I have
- 24 read it during a break.
- Q. The outcome of interest in that study is

- 1 Q. Page 1, title. Do you see where it says 2 "Asbestos Part 1; chrysotile asbestos; regulation of
- 3 certain conditions of use"?
- 4 A. Yeah.
- 5 Q. Okay. Can we flip down to page 15? And I
- 6 think this might be a -- excuse me -- the end of
- 7 page 14. I think this might be a passage that you
- 8 read with Michelle earlier. Let me know when you're
- 9 there.
- 10 MS. PARFITT: Bottom of 14.
- 11 A. Yes
- 12 Q. And I think this is the passage that you
- 13 read: "Additionally, some talc deposits and
- 14 articles containing talc has been shown to contain
- 15 asbestos. The EPA recommends that certain uses of
- 16 talc may present the potential for asbestos
- 17 exposure. Where EPA identifies reasonably available
- 18 information demonstrating the presence of asbestos
- 19 in talc and where such talc applications fall under
- 20 Toxic Substances Control Act authority, those
- 21 applications of asbestos-containing talc conditions
- 22 will be evaluated in Part 2 of the risk evaluation
- 23 for asbestos."
- So would you agree with me this Part 1 of
- 25 the risk evaluation was not focused on talc that may

	Page 290	Page 292
	contain asbestos?	1 WITNESS: Sonal Sing, M.D., M.P.H [Volume I]
2	MS. PARFITT: Objection. Form.	2 DATE: April 4, 2024
3	A. No. They, you know they say they'll do	3 CASE: IN RE JOHNSON & JOHNSON TALCUM POWDER
4	future evaluations. But they also say that talc,	4 PRODUCTS MARKETING, SALES PRACTICES, AND
5	you know, as they state here some talc deposits	5 PRODUCTS LIABILITY LITIGATION
6	and particles containing talc have been shown to	6
7	contain asbestos.	7
8	Q. Would you agree with me that exposure to	8 DISTRIBUTION TO COUNSEL The original signature
9	talcum powder was not the focus of this portion of	9 page/errata sheet was sent to Michelle A. Parfitt,
10	the EPA's review?	10 Esq., to obtain signature from the deponent. When
11	A. No.	11 signed, please send original to Zachary W. Martin,
12	MS. PARFITT: Objection.	12 Esq., who will supply a copy of the signed errata
13	Q. You would not agree with that?	13 sheet to other counsel present at the deposition.
14	A. No. I'm saying that this EPA review is	14
	focusing on asbestos and ovarian cancer and noting	15 WITNESS INSTRUCTIONS After reading the transcript
	when that talc can occur. But they're not	16 of your deposition, please note any change or
17	specifically looking at peroneal talc and cosmetic	17 correction and the reason for it on the errata
	tale.	
19	MR. MARTIN: I don't have anything	18 sheet. DO NOT make any notations on the transcript
	further.	19 itself. Use additional sheets if necessary.
		20
21	MS. PARFITT: Nothing. Thank you very	21 SIGN AND DATE THE ERRATA SHEET under the pains and
	E	22 penalties of perjury and return it, along with the
23	(Deposition concluded at 5:45 p.m.)	23 transcript, to your counsel.
24		24
25		25
	Page 291	Page 293
1	Page 291 REPORTER'S CERTIFICATE	1 IN THE UNITED STATES DISTRICT COURT
1 2	· · · · · · · · · · · · · · · · · · ·	IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY
	· · · · · · · · · · · · · · · · · · ·	1 IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY 2
2	REPORTER'S CERTIFICATE	IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY
2	REPORTER'S CERTIFICATE  I, SONYA LOPES, Registered Professional	1 IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY  2 IN RE JOHNSON & JOHNSON TALCUM  3 POWDER PRODUCTS MARKETING, MDL NO. SALES PRACTICES, AND PRODUCTS 16-2738(MAS)(RLS)
2 3 4	REPORTER'S CERTIFICATE  I, SONYA LOPES, Registered Professional Reporter and Notary Public in and for the	1 IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY 2 IN RE JOHNSON & JOHNSON TALCUM 3 POWDER PRODUCTS MARKETING, MDL NO.
2 3 4 5 6	REPORTER'S CERTIFICATE  I, SONYA LOPES, Registered Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, certify;	1 IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY  2 IN RE JOHNSON & JOHNSON TALCUM  3 POWDER PRODUCTS MARKETING, MDL NO. SALES PRACTICES, AND PRODUCTS 16-2738(MAS)(RLS)  4 LIABILITY LITIGATION
2 3 4 5 6 7	REPORTER'S CERTIFICATE  I, SONYA LOPES, Registered Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, certify; That the foregoing proceedings were taken	1 IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY  2 IN RE JOHNSON & JOHNSON TALCUM  3 POWDER PRODUCTS MARKETING, MDL NO. SALES PRACTICES, AND PRODUCTS 16-2738(MAS)(RLS)
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#### Federal Rules of Civil Procedure Rule 30

- (e) Review By the Witness; Changes.
- (1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:
- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.
- (2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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